

Safety Data Sheet

According to Regulation (EC) No. 1907/2006 (REACH)

Version 2, Issuing Date: 10-JUL-2023

Print Date: 10-JUL-2023

SECTION 1 Identification of the Substance/Mixture and of the Company/Undertaking

1.1. Product identifier

Product Names: Human Male AB Plasma-Derived Serum, Manufactured with Human Thrombin

Product Options: United States, 100ml, 500ml

Product Code: S-HUH-US-011 (100ml), S-HUH-US-015 (500ml)

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

For research or manufacturing use only. Not for use in humans or for clinical diagnosis.

1.3. Details of the supplier of the safety data sheet

Company: Serana Europe GmbH

Dorfstrasse 17A

14641 Pessin

Germany

Phone: +49 (0)332 3785 9253

E-Mail: info@serana-europe.com

1.4. Emergency telephone number

Emergency Phone: Regular Office Hours +49 (0)332 3785 9253

SECTION 2 Hazards Identification

2.1. Classification of the substance or mixture

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

2.2. Label elements

CLP Regulation (EC) No 1272/2008:

Not applicable

2.3. Other hazards

None

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SECTION 3 Composition/Information on Ingredients

3.1. Substances

Chemical characterization: organic compound

The product contains no substances which are considered at their given concentration to be hazardous to health. Although the human plasma used to manufacture this product has been tested and shown to be negative for infectious agents, no test is 100% accurate. All materials derived from human blood should be handled as if capable of transmitting infection.

3.2. Mixture

Not applicable

SECTION 4 First Aid Measures

4.1. Description of first aid measures

In either case, seek medical attention if the symptoms get worse or persist, showing the SDS of this product.

If inhaled

If breathed in, move person into fresh air. If symptoms persist, call a physician. If not breathing, give artificial respiration.

In case of skin contact

Wash off with soap and plenty of water. If symptoms arise, call a physician.

In case of eye contact

Flush eyes with water as a precaution. Rinse immediately with plenty of water, also under eyelids, for at least 15 minutes. If symptoms persist, call a physician.

If swallowed

Never give anything by mouth to an unconscious person. Rinse mouth with water. If symptoms persist, call a physician. Do not induce vomiting without medical advice.

Notes to Physician

Treat symptomatically.

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

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

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

No data available

SECTION 5 Fire-fighting Measures

5.1. Extinguishing media

Suitable extinguishing media

Use extinguishing measures that are appropriate to local circumstances and the surrounding environment (e.g. ABC powder). Water spray, Carbon dioxide (CO₂), Foam, Dry Chemical can be used.

5.2. Special hazards arising from the substance or mixture

Nature of decomposition products not known.

5.3. Advice for firefighters

Wear self-contained breathing apparatus for fire-fighting if necessary.

5.4. Further information

The product itself does not burn.

SECTION 6 Accidental Release Measures

6.1. Personal precautions, protective equipment and emergency procedures

Avoid breathing vapors, mist or gas. For personal protection see section 8.

6.2. Environmental precautions

Do not let product enter drains.

6.3. Methods and materials for containment and cleaning up

Absorb the spillage using sand or inert absorbent material. Keep in suitable, closed containers for disposal.

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6.4. Reference to other sections

For disposal see section 13.

SECTION 7 Handling and Storage

7.1. Precautions for safe handling

Avoid contact with skin, eyes, and clothing. Wear personal protective equipment.

7.2. Conditions for safe storage, including any incompatibilities

Store in cool place. Keep container tightly closed in a dry and well-ventilated place. Containers which are opened must be carefully resealed and kept upright to prevent leakage. Recommended storage temperature: $\leq -15^{\circ}\text{C}$.

7.3. Specific end uses

A part from the uses mentioned in section 1.2. no other specific uses are stipulated.

SECTION 8 Exposure Controls/Personal Protection

8.1. Control parameters

There are no occupational exposure limits for the substances contained in this product.

8.2. Exposure controls

8.2.1. Appropriate engineering controls

General industrial hygiene practice. Ensure adequate ventilation, especially in confined areas.

8.2.2. Personal protective equipment

Personal Protective Equipment requirements are dependent on user institution's risk assessment and are specific for each laboratory where this material may be used.

Eye/face protection

Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

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Skin protection

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands. The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.

Body protection

Impervious clothing. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Respiratory protection

Respiratory protection not required. For nuisance exposures use type OV/AG (US) or type ABEK (EU EN 14387) respirator cartridges. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

8.2.3. Environmental exposure controls

Do not let product enter drains.

SECTION 9 Physical and Chemical Properties

9.1. Information on basic physical and chemical properties

Appearance:	Form: liquid
	Colour: straw to amber color
Odor:	No data available.
Water solubility:	No data available.
Boiling point/Range:	No data available.
Melting point/Range:	No data available.
Flash point:	No data available.
Auto ignition temp.:	No data available.
Oxidizing Properties:	No data available.

9.2. Other safety information

No data available

SECTION 10 Stability and Reactivity

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- 10.1. Reactivity**
No data available.
- 10.2. Chemical stability**
Stable under recommended storage conditions.
- 10.3. Possibility of hazardous reactions**
No data available.
- 10.4. Conditions to avoid**
No data available.
- 10.5. Incompatible materials**
Avoid alkalis or strong bases.
- 10.6. Hazardous decomposition products**
Other decomposition products: No data available.

SECTION 11 Toxicological Information

- 11.1. Information on toxicological effects**
 - Acute toxicity**
Not hazardous
 - Skin corrosion/irritation**
May cause skin irritation in susceptible persons
 - Serious eye damage/eye irritation**
May cause eye irritation with susceptible persons.
 - Respiratory or skin sensitization**
No data available.
 - Germ cell mutagenicity**
No data available.
 - Carcinogenicity**
IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.
 - Reproductive toxicity**
No data available.
 - Specific target organ toxicity – single exposure**
No data available.
 - Specific target organ toxicity – repeated exposure**
No data available.

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Aspiration hazard

No data available.

Potential health effects

Inhalation	May be harmful if inhaled. May cause respiratory tract irritation.
Ingestion	May be harmful if swallowed.
Skin	May be harmful if absorbed through skin. May cause skin irritation.
Eyes	May cause eye irritation.

Signs and Symptoms of Exposure

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

Additional Information

RTECS: 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

PBT/vPvB assessment not available as chemical safety assessment not required/not conducted.

12.6. Other adverse effects

No data available.

SECTION 13 Disposal Considerations

13.1. Waste treatment methods

Product

Offer surplus and non-recyclable solutions to a licensed disposal company.

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Contaminated packaging

Dispose of as unused product.

SECTION 14 Transport Information

14.1. UN-number

ADR/RID: - IMDG: - IATA: -

14.2. UN proper shipping name

ADR/RID: Not dangerous goods

IMDG: Not dangerous goods

IATA: Not dangerous goods

14.3. Transport hazard class(es)

ADR/RID: - IMDG: - IATA: -

14.4. Packaging group

ADR/RID: - IMDG: - IATA: -

14.5. Environmental hazards

ADR/RID: no IMDG Marine pollutant: no IATA: no

14.6. Special precautions for user

No data available.

SECTION 15 Regulatory Information

This safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006.

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

No data available.

15.2. Chemical Safety Assessment

For this product a chemical safety assessment was not carried out.

SECTION 16 Other Information

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state

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of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product.

a) Revised Version:

First version, date of issue: 10-JAN-2022

b) List of Abbreviations:

ADR: European agreement concerning the international carriage of dangerous goods by road

IMDG: International maritime dangerous goods code

IATA: International air transport association

IBC: International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk

vPvB: very persistent and very bioaccumulative

c) References:

<http://echa.europa.eu>

<http://eur-lex.europa.eu>

d) Methods for evaluation of mixtures according to Article 9 of Regulation (EC) No 1272/2008:

No data available.

e) List of hazard and precautionary statements:

If applicable, please see section 2.

f) Training advice:

General laboratory instructions are required. No special training advised.

- END OF SAFETY DATA SHEET -