

SAFETY DATA SHEET

SECTION 1: Identification

Product identifier

Trade name

Albumin (Human) 5%, 20% & 25%

Other means of identification

Human Albumin

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

Relevant identified uses of the substance or mixture

Pharmaceutical Use

Uses advised against

-

Chemical manufacturer

Company and address

Octapharma Pharmazeutika Produktionsges.m.b.H.
Oberlaaer Strasse 235
A-1100 Vienna, Austria

And

Octapharma AB
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SE-112 75 Stockholm, Sweden

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SDS date

09/21/2015

SDS Version

1.0

Emergency telephone number

866-766-4860
See section 4 "First aid measures"

SECTION 2: Hazards identification

Classification of the chemical in accordance with paragraph (d) of §1910.1200

This product is not classified as hazardous.

Signal word, hazard statement(s), symbol(s) and precautionary statement(s) in accordance with paragraph (f) of §1910.1200

Hazard pictogram(s)

-

Signal word

-

Hazard statement(s)

-

Safety statement(s)	General	-
	Prevention	-
	Response	-
	Storage	-

Disposal -

Identity of the substances primarily responsible for the major health hazards

-

Other hazards

Additional warnings

-

VOC

-

SECTION 3: Composition/information on ingredients

Mixtures

Active ingredients: Human albumin

NAME: Albumin (Human) 5%

1000 ml solution contain:

NAME: Protein, of which $\geq 96\%$ is human albumin
 IDENTIFICATION CAS.: -
 CONTENT: 50 g
 CLASSIFICATION: -

NAME: Sodium
 IDENTIFICATION CAS.: -
 CONTENT: 130-160 mmol
 CLASSIFICATION: -

NAME: Potassium
 IDENTIFICATION CAS.: -
 CONTENT: ≤ 2 mmol
 CLASSIFICATION: -

NAME: N-acetyl-DL-tryptophan
 IDENTIFICATION CAS.: 87-32-1
 CONTENT: 0.064-0.096 mmol/g protein
 CLASSIFICATION: -

NAME: Caprylic acid
 IDENTIFICATION CAS.: 124-07-2
 CONTENT: 0.064-0.096 mmol/g protein
 CLASSIFICATION: Skin Corr. 1B, H314

NAME: Water for Injections
 IDENTIFICATION CAS.: -
 CONTENT: ad. 1000 ml
 CLASSIFICATION: -

NAME: Albumin (Human) 20%

1000 ml solution contains:

NAME: Protein, of which $\geq 96\%$ is human albumin
 IDENTIFICATION CAS.: -
 CONTENT: 200 g
 CLASSIFICATION: -

NAME: Sodium
 IDENTIFICATION CAS.: -
 CONTENT: 130-160 mmol
 CLASSIFICATION: -

NAME: Potassium
 IDENTIFICATION CAS.: -
 CONTENT: ≤ 2 mmol
 CLASSIFICATION: -

NAME: N-acetyl-DL-tryptophan
 IDENTIFICATION CAS.: 87-32-1
 CONTENT: 0.064-0.096 mmol/g protein
 CLASSIFICATION: -

NAME: Caprylic acid
 IDENTIFICATION CAS.: 124-07-2
 CONTENT: 0.064-0.096 mmol/g protein
 CLASSIFICATION: Skin Corr. 1B, H314

NAME: Water for Injections
 IDENTIFICATION CAS.: -
 CONTENT: ad. 1000 ml
 CLASSIFICATION: -

NAME: Albumin (Human) 25%

1000 ml solution contains:

NAME: Protein, of which >= 96% is human albumin
 IDENTIFICATION CAS.: -
 CONTENT: 250 g
 CLASSIFICATION: -

NAME: Sodium
 IDENTIFICATION CAS.: -
 CONTENT: 130-160 mmol
 CLASSIFICATION: -

NAME: Potassium
 IDENTIFICATION CAS.: -
 CONTENT: <=2 mmol
 CLASSIFICATION: -

NAME: N-acetyl-DL-tryptophan
 IDENTIFICATION CAS.: 87-32-1
 CONTENT: 0.064-0.096 mmol/g protein
 CLASSIFICATION: -

NAME: Caprylic acid
 IDENTIFICATION CAS.: 124-07-2
 CONTENT: 0.064-0.096 mmol/g protein
 CLASSIFICATION: Skin Corr. 1B, H314

NAME: Water for Injections
 IDENTIFICATION CAS.: -
 CONTENT: ad. 1000 ml
 CLASSIFICATION: -

(*) See full text of H-phrases in chapter 16. Occupational exposure limits are listed in section 8, if these are available.

Other information

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SECTION 4: First aid measures

Description of first aid measures

General information

In the case of accident: Contact a doctor or casualty department – bring this safety data sheet or the product label. Contact a doctor, if in doubt about the injured person's condition or if the symptoms continue. Never give water to an unconscious person.

Inhalation

Move the person into fresh air and stay with them.

Skin contact

Remove contaminated clothing and shoes. Skin in contact with the material must be washed thoroughly with water and soap. Skin cleanser can be used. DO NOT use solvents or thinners.

Eye contact

Remove any contact lenses. Flush eyes immediately with plenty of water (68-86 °F (20-30°C)) and continue until irritation stops. Make sure you flush under the upper and lower eyelids. If irritation continues, contact a doctor.

Ingestion

Give the person plenty of water to drink and stay with the person. If the person feels unwell, contact a doctor immediately and bring this safety data sheet or the product label with you. Do not induce vomiting

unless recommended by the doctor. Hold head facing down so that no vomit runs back into the mouth and throat.

Most important symptoms and effects, both acute and delayed

No special

Indication of any immediate medical attention and special treatment needed

No special

Information to medics

Treat according to local standard protocols. For additional guidance, refer to the current prescribing information or the local poison control information centre. Medical treatment in cases of overexposure should be treated as an overdose of human albumin solution.

Bring this safety data sheet in order to inform medical staff.

SECTION 5: Firefighting measures

Extinguishing media

Recommended: alcohol-resistant foam, carbonic acid, powder, water mist. Water jets should not be used, since they can spread the fire.

Special hazards arising from the substance or mixture

No special.

Advice for firefighters

Wear self-contained breathing apparatus and protective clothing to prevent contact.

SECTION 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures

No specific requirements.

Methods and material for containment and cleaning up

Wipe up with a cloth. Place in container for disposal, according to local regulations. Cleaning should be done as far as possible using normal cleaning agents. Solvents should be avoided.

Care must be taken when removing broken glass vials.

SECTION 7: Handling and storage

Precautions for safe handling

The solution can be directly administered by the intravenous route.

Albumin solutions must not be diluted with water for injections as this may cause haemolysis in recipients.

If large volumes are administered, the product should be warmed to room temperature before use.

Do not use if turbid and/or discoloration is observed.

Conditions for safe storage, including any incompatibilities

Albumin (Human) may be stored for 36 months from the date of manufacture.

Store in the original container to protect from light.

Do not freeze. Do not use after expiration date.

Storage temperature

36°F to 77°F (2°C to 25°C)

SECTION 8: Exposure controls/personal protection

OSHA permissible exposure limit (PEL), American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Value (TLV), and any other exposure limit used or recommended by the chemical manufacturer, importer, or employer preparing the safety data sheet, where available.

OEL

No data available

DNEL / PNEC

No data available.

Appropriate engineering controls

No control is necessary if the product is handled in a normal way.

General recommendations

Observe general occupational hygiene.

Exposure limits

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

Appropriate technical measures

Take ordinary precautions when using the product. Avoid inhalation of gas or dust.

Hygiene measures

Whenever you take a break in using this product and when you have finished using it, all exposed areas of the body must be washed. Always wash hands, forearms and face.

Measures to avoid environmental exposure

No specific requirements.

Individual protection measures, such as personal protective equipment

Respiratory Equipment

No specific requirements.

Skin protection

No specific requirements.

Hand protection

No specific requirements.

Eye protection

No specific requirements.

SECTION 9: Physical and chemical properties

Information on basic physical and chemical properties

Form	Colour	Odour	pH (1% protein solution)	Viscosity	Density (g/cm ³)
Slightly viscous liquid	Clear, almost colourless, yellow, amber or green.	-	6.4-7.4	-	-

Phase changes

Melting point (°C)

-

Boiling point (°C)

-

Vapour pressure (mm Hg)

-

Data on fire and explosion hazards

Flashpoint (°C)

-

Ignition (°C)

-

Self-ignition (°C)

-

Explosion limits (Vol %)

-

Oxidizing properties

-

Solubility

Solubility in water

Soluble

n-octanol/water coefficient

-

Other information

Solubility in fat

-

Additional information

Solution for infusion.

SECTION 10: Stability and reactivity

Reactivity

No data available

Chemical stability

3 years. The product is stable under the conditions, noted in the section on "Handling and storage".

Possibility of hazardous reactions

No special

Conditions to avoid

None for normal handling of this product.

Incompatible materials

Strong acids, strong bases, strong oxidizing agents, and strong reductants agents.

Hazardous decomposition products

The product is not degraded when handled as specified in section 7.

SECTION 11: Toxicological information

Information on toxicological effects

Human albumin is a normal constituent of human plasma and acts like physiological albumin. In animals, single dose toxicity testing is of little relevance and does not permit the evaluation of toxic or lethal doses or of a dose-effect-relationship. Repeated dose toxicity testing is impracticable due to the development of antibodies to heterologous protein in animal models. To date, human albumin has not been reported to be associated with embryofetal toxicity, oncogenic or mutagenic potential. No signs of acute toxicity have been described in animal models.

Information on the likely routes of exposure

No data available.

Symptoms related to the physical, chemical and toxicological characteristics

No data available.

Delayed and immediate effects and also chronic effects from short- and long-term exposure

No data available.

Numerical measures of toxicity

No data available.

Acute toxicity

No data available.

Hazardous chemical is listed in NTP, IARC, OSHA

No classification data on carcinogen properties of this material is available from NTP, IARC or OSHA.

SECTION 12: Ecological information

Ecotoxicity

Being endogenous human constituents all the above active substances will be taken up and enter the natural endogenous pathways for activity and metabolism, and their excretion products are not supposed to be any other than those naturally excreted from the human.

Based on the above considerations all the above products are considered not to pose any threat to the environment.

Substance

No data available.

Persistence and degradability

Substance

No data available.

Bioaccumulative potential

Substance

No data available.

Mobility in soil

No data available

Other adverse effects

No special

SECTION 13: Disposal considerations

Waste treatment methods

Observe all local and national regulations when disposing of this material.

Specific labelling

None

Contaminated packing

No specific requirements.

SECTION 14: Transport information

Not listed as dangerous goods under DOT, IMDG or IATA. The product shall not be transported above 77°F (25 °C). Protect from light. Do not freeze.

DOT

Not Applicable

IMDG

Not Applicable

IATA/CAO

Not Applicable

Environmental hazards

No data available

Special precautions for user

No data available

Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

No data available

SECTION 15: Regulatory information

Safety, health and environmental regulations/legislation specific for the product in question

TSCA listed: All substances are listed

SARA Title III: No SARA Hazards

California Prop. 65 Components: This product does not contain any Proposition 65 chemicals

SECTION 16: Other information, including date of preparation or last revision

Full text of H-phrases as mentioned in section 3

H314 - Causes severe skin burns and eye damage.

Other

It is recommended to hand over this safety data sheet to the actual user of the product. Information in this safety data sheet cannot be used as a product specification.

The information in this safety data sheet applies only to this specific product (mentioned in section 1) and is not necessarily correct for use with other chemicals/products.

A change (in proportion to the last essential change (first cipher in SDS version)) is marked with a blue triangle.

Date of preparation

09/21/2015

**Date of last essential change
(First cipher in SDS version)**

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**Date of last minor change
(Last cipher in SDS version)**

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