

# SAFETY DATA SHEET

## 1. IDENTIFICATION OF THE SUBSTANCE / PREPARATION AND OF THE COMPANY / UNDERTAKING

Material Albumin (Human) 5% & Albumin (Human) 25%

Synonyms Human Albumin

Company Name Manufacturer:  
Octapharma Pharmazeutika Produktionsges.m.b.H.  
Oberlaaer Strasse 235  
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Austria

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## 2. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredients **Active ingredients:** Human albumin

### **Albumin (Human) 5%**

1000 ml solution contain:

Protein, of which $\geq 96\%$ is human albumin	50	g
Sodium	130 - 160	mmol
Potassium	$\leq 2$	mmol
N-acetyl-DL-tryptophan	0.064 - 0.096	mmol/g protein
Caprylic acid	0.064 - 0.096	mmol/g protein
Water for Injections	ad. 1000	ml

### **Albumin (Human) 25%**

1000 ml solution contain:

Protein, of which $\geq 96\%$ is human albumin	250	g
Sodium	130 - 160	mmol
Potassium	$\leq 2$	mmol
N-acetyl-DL-tryptophan	0.064 - 0.096	mmol/g protein
Caprylic acid	0.064 - 0.096	mmol/g protein
Water for Injections	ad. 1000	ml

### 3. HAZARDS IDENTIFICATION

Health	Caution – Pharmaceutical agent.
Environment	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.

### 4. FIRST-AID MEASURES

Ingestion	Do not attempt to induce vomiting. Do not attempt to give any solid or liquid by mouth if the concerned subject is unconscious or semi-conscious. Wash out the mouth with water. If the exposed subject is fully conscious, give plenty of water to drink. Obtain medical attention.
Inhalation	Using appropriate personal protective equipment, move concerned subject to fresh air. If breathing is difficult or ceases, ensure and maintain ventilation. Give oxygen as appropriate. Obtain medical attention in cases with symptoms including disturbed breathing, loss of consciousness, chest pain, marked coughing or other side effects which may be delayed.
Skin Contact	Using appropriate personal protective equipment, flush exposed area with water. Obtain medical attention if skin reaction occurs which may be immediate or delayed.
Eye Contact	Wash with clean and gently flowing water. Continue for about 15 minutes. Obtain medical attention.

### NOTES TO HEALTH PROFESSIONALS

Medical Treatment	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.
Medical Conditions Caused or Aggravated by Exposure	Refer to current prescribing information for detailed description of medical conditions caused or aggravated by overexposure of this product.
Antidotes	No specific antidotes are recommended.

### 5. FIRE-FIGHTING MEASURES

Fire and Explosion Hazards	This product is non-combustible, although the packaging is combustible.
Special Firefighting Procedures	No special requirements needed.
Hazardous Combustion Products	No special requirements needed.

## 6. ACCIDENTAL RELEASE MEASURES

Spills	Care must be taken when removing broken glass vials
Personal Precaution	No personal precautions needed.
Environmental Precautions	n.a.
Clean-up Methods	Water can be used for clean-up.
Decontamination Procedures	There are no decontamination operations needed.

## 7. HANDLING AND STORAGE

Handling	<p>The solution can be directly administered by the intravenous route.</p> <p>Albumin solutions must not be diluted with water for injections as this may cause haemolysis in recipients.</p> <p>If large volumes are administered, the product should be warmed to room temperature before use.</p> <p>Do not use if turbid and/or discoloration is observed.</p>
Storage	<p>Albumin (Human) may be stored for 36 months at +2°C to +25°C (36°F to 77°F) from the date of manufacture.</p> <p>Store in the original container to protect from light.</p> <p>Do not freeze. Do not use after expiration date.</p>

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

INGREDIENT	Human albumin
GSK Occupational Hazard Category	n.a.
GSK Occupational Exposure Limit	n.a.
ENGINEERING CONTROLS	
Exposure Controls	n.a.
Other Equipment or Procedures	None required for normal handling. Wash hands and arms thoroughly after handling.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	
Clarity	Clear, slightly viscous liquid.
Colour	Colourless or slightly yellow or green.
Physical Form	Solution for infusion.
pH (1% protein solution)	6.4 – 7.4

## 10. STABILITY AND REACTIVITY

Stability	3 years
Conditions to Avoid	None for normal handling of this product.

## 11. TOXICOLOGICAL INFORMATION

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 embryo-foetal toxicity, oncogenic or mutagenic potential.

No signs of acute toxicity have been described in animal models.

## 12. ECOLOGICAL INFORMATION

Summary	see "3. HAZARDS IDENTIFICATION/Environment"
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## 13. DISPOSAL CONSIDERATIONS

Disposal Recommendations	Collect for recycling or recovery if possible. The disposal method for rejected products/returned goods must ensure that they cannot be re-sold or re-used.
Regulatory Requirements	Observe all local and national regulations when disposing of this material.

## 14. TRANSPORT INFORMATION

UN Classification and Labelling	
Transport Information	The product shall be transported not above +25 °C (77°F). Protect from light. Do not freeze.

## 15. REGULATORY INFORMATION

EU Classification and Labelling	
Classification(s)	Pharmacotherapeutic group: plasma substitutes and plasma protein fractions, ATC code: B05A A01

## 16. OTHER INFORMATION

Date Approved/Revised	20.10.2006
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