

# SAFETY DATA SHEET

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

Material Wilate

Synonyms von Willebrand Factor/Coagulation Factor VIII Complex (Human), freeze dried

Company Name Manufacturer:  
Octapharma Pharmazeutika Produktionsges.m.b.H.  
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## 2. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredients **Active ingredients:**  
von Willebrand factor (VWF) and coagulation factor VIII (FVIII) (Human)

<b><u>Component</u></b>	<b><u>Quantity/ 5 mL vial</u></b>	<b><u>Quantity/ 10 mL vial</u></b>
VWF:RCo	450 IU	900 IU
FVIII	450 IU	900 IU
Total protein	≤ 7.5 mg	≤ 15.0 mg
Glycine	50 mg	100 mg
Sucrose	50 mg	100 mg
Sodium chloride	117 mg	234 mg
Sodium citrate	14.7 mg	29.4 mg
Calcium chloride	0.8 mg	1.5 mg
Water for injection	5 mL	10 mL
Polysorbate 80	1 mg/mL	1 mg/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 the above product is 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 an human immunoglobulin.
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 Fire Fighting 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. For clean up water can be used.
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	Warm the Powder and Diluent in the closed vials up to room temperature. This temperature should be maintained during reconstitution.
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Storage: Store Wilate for up to 36 months at +2°C to +8°C (36°F to 46°F) protected from light from the date of manufacture. Within this period, Wilate may be stored for a period of up to 6 months at room temperature (maximum of +25°C or 77°F). The starting date of room temperature storage should be clearly recorded on the product carton. Once stored at room temperature, the product must not be returned to the refrigerator. The shelf-life then expires after the storage at room temperature, or the expiration date on the product vial, whichever is earliest. Do not freeze.

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

INGREDIENT	von Willebrand factor (VWF) and coagulation factor VIII (FVIII) (Human)
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	-
Colour	A white or pale yellow powder or friable solid
Physical Form	Freeze dried powder for preparation of solution for infusion
pH of Aqueous Solutions	6.8 – 7.4

## 10. STABILITY AND REACTIVITY

Stability:	36 months. Store Wilate for up to 36 months at +2°C to +8°C (36°F to 46°F) protected from light from the date of manufacture. Within this period, Wilate may be stored for a period of up to 6 months at room temperature (maximum of +25°C or 77°F). The starting date of room temperature storage should be clearly recorded on the product carton. Once stored at room temperature, the product must not be returned to the refrigerator. The shelf-life then expires after the storage at room temperature, or the expiration date on the product vial, whichever is earliest. Do not freeze.
Conditions to Avoid	None for normal handling of this product.

## 11. TOXICOLOGICAL INFORMATION

FVIII and VWF in Wilate are normal constituents of the human plasma and act like the endogenous FVIII/VWF.

Single dose toxicity testing of Wilate in mice (intravenous administration route) revealed no test item related adverse effects or pathological alterations at several doses up to 5000 IU/kg b.w..

Intravenous and intra-arterial administration of Wilate into rabbits was well tolerated. Paravenous injections caused a minimal local irritation in one animal.

Repeated injections of Wilate over 14 days into rabbits lead to antibody formation against human (heterologous) protein with corresponding fully reversible clinical and pathohistological effects.

Long term clinical experience provides no hint for tumorigenic and mutagenic effects of human FVIII/VWF.

Wilate contains trace amounts of the chemicals tri(n-butyl)phosphate and Octoxynol (Triton X-100), which are used for solvent/detergent (S/D) viral inactivation during manufacturing. However, preclinical data revealed no hazard for humans based on conventional preclinical studies.

## 12. ECOLOGICAL INFORMATION

Summary see "3. HAZARDS IDENTIFICATION/Environment

## 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. REGULATORY INFORMATION

EU Classification and Labelling Pharmacotherapeutic group: Antihæmorrhagics:  
Classification(s) blood coagulation factors: Von Willebrand factor and coagulation factor VIII in combination

## 15. OTHER INFORMATION

Date Approved/Revised March 2010