

## SAFETY DATA SHEET

Safety data sheet according to (EC) No. 1907/2006.

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**SECTION 1: Identification of the substance/mixture and of the company/undertaking**


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**1.1. Product identifier:****Desmopressin Acetate****1.2. Relevant identified uses of the substance or mixture and uses advised against:**

For medical and veterinary research and/or commercial use. Restricted to professional users.

**1.3. Details of the supplier of the safety data sheet:**

Polypeptide Laboratories AB

Högerudsgatan 21, PO Box 30089 Phone: +46 (0) 40 36 62 00

SE-200 61 Limhamn Fax: +46 (0) 40 36 63 86

Sweden

Responsible person for the safety data sheet (e-mail): [ppl@polypeptide.com](mailto:ppl@polypeptide.com)

**1.4. Emergency telephone:**

Sweden: Acute: 112 – Ask for the Poison Information Centre. In less acute cases: 010 4566700 (Direct Numbers to the Poison Information Centre).

UK: NHS (England or Wales): Dial 111 or 0845 4647 NHS 24 (Scotland): Dial 111

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**SECTION 2: Hazards identification**


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**2.1. Classification of the substance or mixture:**

Desmopressin is a synthetic analogue of vasopressin (a naturally occurring vasoconstrictor in man).

Special caution should always be taken in the handling of biologically active material or materials similar to those.

CLP (1272/2008): None.

**2.2. Label elements:**

EUH210: Safety data sheet available on request.

P260: Do not breathe dust.

**2.3. Other hazards:**

PBT/vPvB: The substance is not considered PBT/vPvB according to criteria in Annex XIII.

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**SECTION 3: Composition/information on ingredients**


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**3.1. Substances:**

% w/w	Substance name	CAS-no.	EC-no.	Index-no.	REACH reg.no.	Classification	Note
86 - 100	Desmopressin	16679-58-6	240-726-7	-	-	None	-
3-8	Acetic Acid	64-19-7	200-580-7	607-002-00-6	-	Flam. Liq. 3;H226 Skin Corr. 1A;H314 Eye Dam. 1;H318	1
≤0,5	Ethanol	64-17-5	200-578-6	603-002-00-5	-	Flam. Liq. 2;H225 Eye Irrit. 2;H319	1

1) The substance has an occupational exposure limit.

Wording of hazard statements - see section 16

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## SECTION 4: First-aid measures

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### 4.1. Description of first aid measures:

In case of a suspected Desmopressin exposure: **Avoid excessive drinking** until it is obvious there are no signs of water retention.

Inhalation: Move the affected person to fresh air. Keep at rest. If needed: Seek medical advice.

Skin contact: Remove contaminated clothing and wash skin with water and mild soap. If irritation persists: Seek medical advice.

Eye contact: Flush with water or physiological salt water, holding eye lids open, remember to remove contact lenses, if any. If irritation persists: Seek medical advice.

Ingestion: Rinse mouth. Avoid drinking water. Seek medical advice.

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

Asthma symptoms, breathing difficulties and allergic skin reaction might be possible in sensitised individuals.

Headache, nausea and abdominal pain.

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

Show this safety data sheet to a physician or emergency ward.

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## SECTION 5: Fire-fighting measures

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### 5.1. Extinguishing media:

Use water spray (never water jet), dry chemical, foam or carbon dioxide.

### 5.2. Special hazards arising from the substance or mixture:

Do not inhale smoke fumes. In case of fire, the product may form hazardous decomposition products: Oxides of carbon-, sulphur- and nitrogen.

### 5.3. Advice for fire-fighters:

Use breathing apparatus with an independent source of air.

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## SECTION 6: Accidental release measures

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### 6.1. Personal precautions, protective equipment and emergency procedures:

Use personal protective equipment - see section 8. Avoid generation of dust. Ventilate area of leak.

### 6.2. Environmental precautions:

Do not empty into drains – see section 12. Inform appropriate authorities in accordance with local regulations.

### 6.3. Methods and material for containment and cleaning up:

Sweep up and place in a suitable container. Flush area of spill with plenty of water. Further handling of spillage - see section 13.

### 6.4. Reference to other sections:

See above.

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## SECTION 7: Handling and storage

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### 7.1. Precautions for safe handling:

Avoid breathing dust. Provide adequate ventilation e.g. by working in a fumehood. Do not open until use. Avoid contact with skin, eyes and clothing. Avoid generation of dust and spreading. Wash contaminated skin with water and mild soap. Change contaminated clothing immediately. Take precautionary measures against static discharges. Required access to water and eye wash fountain

### 7.2. Conditions for safe storage, including any incompatibilities:

Store in a tightly closed original container at 2-8°C in a dry and well-ventilated place. Avoid exposure to light.

See also manufacturer's specifications.

### 7.3. Specific end use(s):

See section 1

## SECTION 8: Exposure controls/Personal protection

### 8.1. Control parameters:

	NGV:		KGV:		Anm.
	ppm	mg/m <sup>3</sup>	ppm	mg/m <sup>3</sup>	
Sweden: AFS 2015:7:					
Acetic acid	5	13	0	25	V
Ethanol	500	1000	1000	1900	V

V = Vägledande korttidsgränsvärde

UK: Occupational exposure limits (EH40/2005 with later amendments):

	TWA		STEL		Comments
	ppm	mg/m <sup>3</sup>	ppm	mg/m <sup>3</sup>	
Ethanol	1000	1920	-	-	-
Desmopressin	0.2 µg/m <sup>3</sup> (OEL calculated by Ferring)				

DNEL/PNEC: No CSR.

### 8.2. Exposure controls:

Appropriate engineering controls: Provide adequate ventilation e.g. by working in a fumehood.

Personal protective equipment:

Respiratory protection: During all open handling use an approved mask (EN149) with a particle filter type P3. The filter has a limited lifetime and must be changed. Read the instruction.

Skin protection: Wear protective gloves (EN374) of e.g. nitrile rubber. It has not been possible to find any data for breakthrough time, so it is recommended to change the glove if spilled on.

Eye protection: Wear tightly fitting safety goggles (EN166) in case of risk of contact with the eyes

Environmental exposure controls: None particular.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties:

Appearance:	White powder
Odour:	Slight smell of acetic acid
Odour threshold:	No available data
pH (1% aqueous solution):	4.5 - 5.0
Melting point/freezing point (°C):	Decomposes when heated
Initial boiling point and boiling range (°C):	Not applicable
Flash point (°C):	Not applicable
Evaporation rate:	Not applicable
Flammability (solid, gas):	No available data
Upper/lower flammability or explosive limits (vol.-%):	No available data
Vapour pressure:	Not applicable
Relative density:	No available data
Solubility (water):	Soluble
Partition coefficient: n-octanol/water:	No available data
Auto-ignition temperature (°C):	No available data
Decomposition temperature (°C):	No available data
Viscosity:	Not applicable
Explosive properties:	Dust may form explosive mixture with air.
Oxidising properties:	No available data
9.2. Other information:	None relevant

## SECTION 10: Stability and reactivity

### 10.1. Reactivity:

No available information.

### 10.2. Chemical stability:

Stable under normal conditions - see section 7. Combustible.

### 10.3. Possibility of hazardous reactions:

Dust may form explosive mixture with air.

### 10.4. Conditions to avoid:

Strong heat, light and moisture. Avoid generation of dust.

### 10.5. Incompatible materials:

None known.

### 10.6. Hazardous decomposition products:

When heated to high temperatures (decomposition) toxic fumes are emitted: Oxides of carbon-, sulphur- and nitrogen.

## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects:

Hazard class	Data	Test	Data source
Acute toxicity:			
Inhalation	LC <sub>50</sub> (rat) = 11,4 mg/l (Acetic acid)	No info	IUCLID
Dermal	LC <sub>50</sub> (rat) = 11,4 mg/l (Acetic acid)	No info	IUCLID
Oral	LD <sub>50</sub> (rat) = 3310 mg/kg (Acetic acid)	No info	IUCLID
Corrosion/irritation:	Severe irritation to corrosion of skin and eyes, rabbit (Acetic acid)	No info	IUCLID
Sensitization:	No available/applicable data.	-	-
CMR:	No mutagenic effect (Desmopressin) No effect on fertility, embryonic and foetal development, or peri- and postnatal development (Desmopressin) TD <sub>Lo</sub> (rat, oral) = 5760 mg/kg/32W intermittent: "Equivocal tumorigenic agent" (Acetic acid) TD <sub>Lo</sub> (lactating female rat, oral) = 700 mg/kg 18d after birth: "Effects on new-born" (Acetic acid)	Ames No info  No info No info	Ferring Ferring  RTECS RTECS

Information on likely routes of exposure: Inhalation and ingestion.

Symptoms:

**Inhalation:** May cause irritation of the mucous membranes. Desmopressin has strong anti-diuretic properties. Symptoms may include headache, nausea, vomiting, diarrhoea, abdominal pain and cramps. Heavy exposure may cause constriction of peripheral blood vessels and contraction of smooth muscle of intestines.

**Skin:** May cause slight irritation.

**Eyes:** May cause irritation.

**Ingestion:** See under "Inhalation".

**Chronic effects:** May cause reduction of urinary excretion. Repeated or prolonged exposure, when combined with uncontrolled and excessive drinking, may cause water retention. May cause sensitization by inhalation and skin contact.

Special caution should always be taken in the handling of polypeptides with hormone-like effects.

Diluted acetic acid may cause eczema by prolonged or repeated skin contact. Prolonged exposure to acetic acid vapours may cause nasal and pharyngeal inflammation, chronic bronchitis and corrosive damage to the teeth. Prolonged or frequent exposure to vapours of volatile organic compounds may result in damage on liver, kidneys, blood or central nervous system (including brain damage).

## SECTION 12: Ecological information

### 12.1. Toxicity:

Akvatisk	Data (Acetic acid)	Test (Medie)	Data source
Fish	LC <sub>50</sub> (Oncorhynchus mykiss, 96h) > 300 mg/l	OECD 203	ECHA
Daphnia	EC <sub>50</sub> (Acartia tonsa, 48h) > 300 mg/l	OECD 202	ECHA
Algae	EC <sub>50</sub> (Skeletonema costatum, 72h) > 1000 mg/l	ISO 10253	ECHA

### 12.2. Persistence and degradability:

Acetic acid is rapidly degradable (OECD 301).

### 12.3. Bioaccumulative potential:

Acetic acid: Log K<sub>ow</sub> <1 (no bioaccumulation).

### 12.4. Mobility in soil:

No available/applicable data.

### 12.5. Results of PBT and vPvB assessment:

The substance is not considered PBT/vPvB according to criteria in Annex XIII.

### 12.6. Other adverse effects:

None known.

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods:

Disposal should be according to local, state or national legislation. Dispose of through authority facilities or pass to chemical disposal company.

**EWC-code:** 07 05 99

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## SECTION 14: Transport information

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Not hazardous for transportation (ADR/RID/IMDG/IATA)

**14.1. UN-no.:** None

**14.2. UN proper shipping name:** None

**14.3. Transport hazard class(es):** None

**14.4. Packing group:** None

**14.5. Environmental hazards:** None.

**14.6. Special precautions for user:** None.

**14.7. Transport in bulk according to Annex II of MARPOL and the IBC Code:** Not relevant.

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## SECTION 15: Regulatory information

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

It is advisable not to let pregnant women work with Desmopressin.

It is advisable not to let persons under 18 years of age work with Desmopressin.

Please contact national authorities regarding notification and use of the substance (Directive 2001/82/EC).

Desmopressin is on WADA's list of prohibited doping substances (The World Anti-Doping Code): Group S5, DIURETICS AND MASKING AGENTS.

**15.2. Chemical Safety Assessment:**

No CSR.

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## SECTION 16: Other information

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**Hazard statements mentioned in section 3:**

H225: Highly flammable liquid and vapour.

H226: Flammable liquid and vapour.

H314: Causes severe skin burns and eye damage.

H318: Causes serious eye damage.

H319: Causes serious eye irritation.

**Abbreviations:**

CMR = Carcinogenicity, mutagenicity and reproductive toxicity.

CSR = Chemical Safety Report

DNEL = Derived No-Effect Level

EC<sub>50</sub> = Effect Concentration 50 %

FW = Freshwater

LC<sub>50</sub> = Lethal Concentration 50 %

LD<sub>50</sub> = Lethal Dose 50 %

PBT = Persistent, Bioaccumulative, Toxic

PNEC = Predicted No-Effect Concentration

vPvB = very Persistent, very Bioaccumulative

**Literature:**

ECHA = REACH Registration dossier from ECHA's homepage.

IUCLID = International Uniform Chemical Database Information

RTECS = Register of Toxic Effects of Chemical Substances

<http://pro.medicin.dk>

**Training advice:**

No special training is required. However, the user should be well instructed in the execution of his/her task, be familiar with this Safety Data Sheet and have normal training in the use of personal protective equipment.

**Additional information:**

Prepared based on the information available to Altos A/S January 2020.

**Changes since the previous edition:**

1-16

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