

SAFETY DATA SHEET

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

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

1.1. Product identifier:**Atosiban****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

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

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture:

Atosiban is a peptide analogue of oxytocin with oxytocin antagonist properties.

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.

2.3. Other hazards:

None known. PBT/vPvB: The substance is not considered PBT/vPvB according to criteria in Annex XIII.

SECTION 3: Composition/information on ingredients

3.2. Mixtures:

% w/w	Substance name	CAS	EC-no.	Index-no.	REACH-reg.no.	Classification
90	Atosiban	90779-69-4	Polymer	-	-	Not classified
5	Acetic acid	64-19-7	200-580-7	607-002-00-6	-	Flam. Liq. 3;H226 Skin Corr. 1A;H314

Wording of hazard statements - see section 16.

SECTION 4: First-aid measures

4.1. Description of first aid measures:

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 and drink plenty of water. If needed: Seek medical advice.

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

May cause nausea, vomiting, headache, dizziness, tachycardia, hypotension and hot flashes.

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

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

SECTION 5: Fire-fighting measures

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: Carbon-, sulphur- and nitrogen oxides.

5.3. Advice for fire-fighters:

Use breathing apparatus with an independent source of air.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures:

Use personal protective equipment - see section 8. Avoid generation of dust and spreading. 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.

SECTION 7: Handling and storage

7.1. Precautions for safe handling:

Do not open until use. Avoid contact with skin, eyes and clothes. Avoid generation of dust and spreading. Provide sufficient ventilation. Wash contaminated skin immediately with water and mild soap. Take precautionary measures against static discharges.

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. In addition see manufacturer's specifications.

7.3. Specific end use(s):

See section 1.

SECTION 8: Exposure controls/Personal protection

8.1. Control parameters:

Sweden: AFS 2015:7:

	NGV:		KGV:		Anm.
	ppm	mg/m ³	ppm	mg/m ³	
Acetic acid	5	13	0	25	V

V = Vägledande korttidsgränsvärde

UK: Occupational exposure limits (EH40/2005 with later amendments): None

Atosiban 0.066 mg/m³ (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 to off-white powder
Odour:	No available data
Odour threshold:	No available data
pH (aqueous solution):	4.5-5.0
Melting point/freezing point (°C):	No available data
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.

10.3. Possibility of hazardous reactions:

Dust may form explosive mixture with air.

10.4. Conditions to avoid:

Strong heat, direct sunlight and moisture. Avoid generation of dust.

10.5. Incompatible materials:

Bases and strong acids.

10.6. Hazardous decomposition products:

When heated to high temperatures (decomposition) toxic fumes are emitted: Carbon-, sulphur- and nitrogen oxides.

SECTION 11: Toxicological information

11.1. Information on toxicological effects:

Hazard class	Data	Test	Data source
Acute toxicity:			
Inhalation	LC ₅₀ (rat) = 11,4 mg/l (Acetic acid)	No info	IUCLID
Dermal	LC ₅₀ (rat) = 11,4 mg/l (Acetic acid)	No info	IUCLID
Oral	LD ₅₀ (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 CMR effects (Atosiban)	No info	Ferring
	TD _{Lo} (rat, oral) = 5760 mg/kg/32W intermittent: "Equivocal tumorigenic agent" (Acetic acid)	No info	RTECS
	TD _{Lo} (lactating female rat, oral) = 700 mg/kg 18d after birth: "Effects on new-born" (Acetic acid)	No info	RTECS

Information on likely routes of exposure: Inhalation, skin and ingestion.

Symptoms:

Inhalation: May cause irritation of the respiratory tract. May cause nausea, vomiting, headache, dizziness, tachycardia, hypotension, hot flashes.

Skin: May cause slight irritation.

Eyes: May cause irritation.

Ingestion: See under "Inhalation". After oral administration proteolysis/degradation and hence no bioavailability is expected.

Chronic effects: Peptides may cause potential antigenicity and allergic reactions. Special caution should always be taken in the handling of polypeptides with hormone-like effects. May cause deviations from the normal progress of pregnancy and labour. 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 ₅₀ (Oncorhynchus mykiss, 96h) = >300 mg/l	OECD 203	ECHA
Daphnia	EC ₅₀ (Acartia tonsa, 48h) = >300 mg/l	OECD 202	ECHA
Algae	EC ₅₀ (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_{ow} <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

SECTION 14: Transport information

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.

SECTION 15: Regulatory information

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

It is advisable not to let pregnant women work with the substance. The employer shall assess the working conditions and, if there is any risk to the safety or health and any effects on the pregnancy or breastfeeding of workers, take the necessary measures to adjust the working conditions (Directive 92/85/EEC).

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

15.2. Chemical Safety Assessment:

No CSR.

SECTION 16: Other information

Hazard statements mentioned in section 2 and 3:

H226: Flammable liquid and vapour.

H314: Causes severe skin burns and eye damage.

EUH210: Safety data sheet available on request.

Abbreviations:

CMR = Carcinogenicity, mutagenicity and reproductive toxicity.

CSR = Chemical Safety Report

DNEL = Derived No-Effect Level

EC₅₀ = Effect Concentration 50 %

FW = Freshwater

LC₅₀ = Lethal Concentration 50 %

LD₅₀ = 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.

EPA Ecotox = Environmental Protection Agency

IUCLID = International Uniform Chemical Database Information

RTECS = Register of Toxic Effects of Chemical Substances

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 October 2017

Changes since the previous edition:

Minor changes in section 1-16

Prepared by: Altos a/s – Tonsbakken 16-18 - 2740 Skovlunde - Phone +45 - 38 34 77 98 / AP - Quality control: PW