

## 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:

##### Carbetocin

CAS-no.: 37025-55-1

EC-no.: 253-312-6

INDEX-no.: None

REACH-REG.-no.: None.

#### 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:

Harmful and sensitizing substance, that may harm the unborn child.

Carbetocin is a synthetic analogue of Oxytocin (a naturally occurring hormone in women).

Oxytocin induces uterine contractions and may cause termination of pregnancy. Overexposure can be fatal to the mother and the unborn child.

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

CLP (1272/2008): Acute Tox. 4;H312+H332 Skin Sens. 1;H317 Repr. 2;H361d

#### 2.2. Label elements:



**WARNING**

Content: Carbetocin

H312+H332: Harmful in contact with skin or if inhaled.

H317: May cause an allergic skin reaction.

H361d: Suspected of damaging the unborn child.

P201: Obtain special instructions before use.

P261: Avoid breathing dust.

P280: Wear protective gloves/eye protection/face protection.

P302+P352: IF ON SKIN: Wash with plenty of water.

P308+P313: IF exposed or concerned: Get medical advice/attention.

P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing.

**2.3. Other hazards:** People with kidney or heart diseases should take care in case of application of the substance. May cause irregular heartbeat, postpartum haemorrhage, anaphylactic reactions.

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
90-100	Carbetocin	37025-55-1	253-312-6	-	-	Acute Tox. 4;H312+H332 Skin Sens. 1;H317 Repr. 2;H361d

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 Carbetocin 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. Do not induce vomiting. Seek medical advice immediately.

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

Nausea, vomiting, abdominal pain, hypotension, headache and water retention. Carbetocin induces uterine contractions and may cause termination of pregnancy. May cause an allergic reaction.

### 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:

o not inhale smoke fumes. In case of fire, the product may form hazardous decomposition: Carbon, sulphur- and nitrogen oxides.

### 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 and spreading. Ventilate area of lea or spill.

### 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 immediately 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. In addition see manufacturer's specifications.

Store securely and out of reach of unauthorized personnel and separated from food, feed, drugs etc

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

See section 1

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## SECTION 8: Exposure controls/Personal protection

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### 8.1. Control parameters:

Sweden: AFS 2015:7: None

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

Carbetocin 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.

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## SECTION 9: Physical and chemical properties

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

Appearance:	White to off-white powder
Odour:	Light smell of acetic acid
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
<b>9.2. Other information:</b>	None relevant

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## SECTION 10: Stability and reactivity

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### 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: Carbon, sulphur- and nitrogen oxides.

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## SECTION 11: Toxicological information

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### 11.1. Information on toxicological effects:

No mutagenic effects in in vitro and in vivo tests (Ferring).

No further available/applicable toxicological data.

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

Symptoms:

Inhalation: Uterine cramps of a menstrual character, nausea, vomiting, abdominal pain, hypotension, headache, water retention.

Skin: Harmful in contact with skin.

Eyes: Irritation with redness and pain.

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

Chronic effects: Induces uterine contractions and may cause termination of pregnancy. May cause reduction of urinary excretion. Repeated or prolonged exposure combined with excessive drinking, may cause water retention. Peptides may cause potential antigenicity and allergic reactions. Special caution should always be taken in the handling of polypeptides with hormone-like effects

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## SECTION 12: Ecological information

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### 12.1. Toxicity:

No available/applicable data.

### 12.2. Persistence and degradability:

No available/applicable data.

### 12.3. Bioaccumulative potential:

No available/applicable data.

### 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.

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## SECTION 13: Disposal considerations

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### 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:

Must not be used by persons under 18 years of age.

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).

### 15.2. Chemical Safety Assessment:

No CSR.

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## SECTION 16: Other information

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### Hazard statements mentioned in section 2 and 3:

H312: Harmful in contact with skin.

H332: Harmful if inhaled.

H317: May cause an allergic skin reaction.

H361d: Suspected of damaging the unborn child.

### 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.

EPA Ecotox = Environmental Protection Agency

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 Alttox A/S October 2019

### Changes since the previous edition:

Layout update and new OEL, section 8.

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