

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:****Degarelix**

CAS-no.: 214766-78-6

EC-no.: 807-277-4

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:**

Substance that may impair fertility and harm the unborn child.

Degarelix is an analogue of gonadorelin which is the synthetic form of GnRH (hypothalamic gonadotropin-releasing hormone in man).

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

CLP (1272/2008): Repr. 1A;H360

2.2. Label elements:

Restricted to professional users.

**DANGER**

Content: Degarelix

H360: May damage fertility or the unborn child

P201: Obtain special instructions before use.

P260: Do not breathe dust.

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

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

P405: Store locked up.

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**3.1. Substances:**

% w/w	Substance name	CAS	EC-no.	Index-no.	REACH reg.no.	Classification
~ 100	Degarelix	214766-78-6	807-277-4	-	-	Repr. 1A;H360

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. 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. Seek medical advice.

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

Bone pain, hot flushes, headache, rash and flu-like symptoms. Degarelix impairs fertility and harm the unborn child. May cause reduced libido.

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. 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:

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 in a dry, cool and well-ventilated place. Avoid exposure to light. In, addition see manufacturer's specifications.

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

7.3. Specific end use(s):

See section 1.

SECTION 8: Exposure controls/Personal protection

8.1. Control parameters:

Sweden: AFS 2015:7: None

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

Degarelix 100 ng/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 amorphous powder
Odour:	No available data
Odour threshold:	No available data
pH (aqueous solution):	5.3
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. 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:

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	No available/applicable data	-	-
Dermal	No available/applicable data	-	-
Oral	No available/applicable data	-	-
Corrosion/irritation:	No available/applicable data	-	-
Sensitization:	No available/applicable data	-	-
CMR:	No evidence of carcinogenicity in mouse and rats No evidence of gene mutation or chromosomal abnormalities. Reversible deprivation of sex hormones and impairment of fertility Abortion, early embryo/foetal death, premature delivery and increased duration of parturition in rabbits	No info Ames, Mouse lymphoma assay, in vivo micronucleus test Preclinical and clinical trials No info	Ferring Ferring Ferring Ferring

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

Symptoms:

Inhalation: Inhalation of dust might irritate the respiratory system and cause coughing. Inhalation of dust has several effects on the gonads. Symptoms may include fatigue, hot flushes, Bone pain, headache, rash, flu-like symptoms, menstrual irregularities, insomnia and headache.

Skin: May cause slight irritation.

Eyes: May cause irritation.

Ingestion: See under "Inhalation".

Chronic effects: Degarelix impairs fertility and harm the unborn child. It may cause changes in sex hormones, reduced libido and abortion. Peptides may cause potential antigenicity and allergic reactions. Special caution should always be taken in the handling of polypeptides with hormone-like effects.

SECTION 12: Ecological information

12.1. Toxicity:

Aquatic	Data	Test (Media)	Data source
Fish	LC ₅₀ (Danio rerio, 96h) = >1.4 mg/l	OECD TG 203 (FW)	PolyPeptides
Daphnia	EC ₅₀ (Daphnia magna, 48h) = 80-91 mg/l	OECD TG 202 (FW)	PolyPeptides
	NOEC (Daphnia magna, 21d) = 1.1 mg/l	OECD TG 211 (FW)	PolyPeptides
Algae	EC ₅₀ (Pseudokirchneriella sub. 72h) = 1.4 mg/l	OECD TG 201 (FW)	PolyPeptides

12.2. Persistence and degradability:

Degarelix is not readily biodegradable (OECD 301F).

12.3. Bioaccumulative potential:

Log K_{ow} = 1.16 - Moderate bioaccumulation.

12.4. Mobility in soil:

K_{oc} = 2672 - Limited mobility is expected in soil.

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:

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).

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

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

Degarelix is on WADA's list of prohibited doping substances (The World Anti-Doping Code): Group S2, PEPTIDE HORMONES, GROWTH FACTORS, RELATED SUBSTANCES, AND MIMETICS; Chorionic Gonadotrophin (CG) and Luteinizing Hormone (LH) and their releasing factors.

15.2. Chemical Safety Assessment:

No CSR.

SECTION 16: Other information

Hazard statements mentioned in section 2 and 3:

H360: May damage fertility or the unborn child

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

<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 2017

Changes since the previous edition:

Section 2 and 3. Minor changes in section 1-16

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