

**Safety Data Sheet**

according to Regulation (EC) No 1907/2006

Revision date: 16.07.2020

**Degarelix acetate salt**

Product code: 4047459

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**SECTION 1: Identification of the substance/mixture and of the company/undertaking****1.1. Product identifier**

Degarelix acetate salt

Substance name: Degarelix acetate salt

CAS No: 214766-78-6

**1.2. Relevant identified uses of the substance or mixture and uses advised against****Use of the substance/mixture**

Laboratory chemicals

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

Company name:	Bachem AG	
Street:	Hauptstrasse 144	
Place:	CH-4416 Bubendorf	
Telephone:	+41 58 595 2021	Telefax: +41 58 595 2040
e-mail (Contact person):	msds@bachem.com	
Responsible Department:	Department: Global Marketing	

**1.4. Emergency telephone number:** +41 44 251 51 51 (Tox Info Suisse)**SECTION 2: Hazards identification****2.1. Classification of the substance or mixture****Regulation (EC) No. 1272/2008**

Hazard categories:  
Reproductive toxicity: Repr. 1A  
Hazard Statements:  
May damage fertility or the unborn child.

**2.2. Label elements****Regulation (EC) No. 1272/2008**

Signal word: Danger

Pictograms:

**Hazard statements**

H360 May damage fertility or the unborn child.

**Precautionary statements**

P201	Obtain special instructions before use.
P202	Do not handle until all safety precautions have been read and understood.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P308+P313	IF exposed or concerned: Get medical advice/attention.
P405	Store locked up.
P501	Dispose of contents/container to an appropriate recycling or disposal facility.

**SECTION 3: Composition/information on ingredients****3.1. Substances**

Sum formula:	C82H103CIN18O16
Molecular weight:	1632.28

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**Hazardous components**

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	GHS Classification			
214766-78-6	Degarelix acetate salt			100 %
	Repr. 1A; H360			

Full text of H and EUH statements: see section 16.

**SECTION 4: First aid measures****4.1. Description of first aid measures****General information**

Change contaminated, saturated clothing. In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible).

**After inhalation**

IF INHALED: Remove person to fresh air and keep comfortable for breathing. Get medical advice/attention if you feel unwell.

**After contact with skin**

Rinse cautiously with water for several minutes. If medical advice is needed, have product container or label at hand.

**After contact with eyes**

In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

**After ingestion**

IF SWALLOWED: rinse mouth. Never give anything by mouth to an unconscious person or a person with cramps. Get medical advice/attention if you feel unwell.

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

No information available.

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

No information available.

**SECTION 5: Firefighting measures****5.1. Extinguishing media****Suitable extinguishing media**

Dry extinguishing powder

**Unsuitable extinguishing media**

No information available.

**5.2. Special hazards arising from the substance or mixture**

Carbon monoxide Carbon dioxide (CO<sub>2</sub>) Nitrogen oxides (NO<sub>x</sub>) Hydrogen chloride (HCl)

**5.3. Advice for firefighters**

Wear a self-contained breathing apparatus and chemical protective clothing.

**Additional information**

Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water.

**SECTION 6: Accidental release measures****6.1. Personal precautions, protective equipment and emergency procedures**

Provide adequate ventilation. Use personal protection equipment. Avoid contact with skin, eyes and clothes. Do not breathe dust/fume/gas/mist/vapours/spray. Remove persons to safety.

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**6.2. Environmental precautions**

Do not allow to enter into surface water or drains. Cover drains.

**6.3. Methods and material for containment and cleaning up**

Collect spillage. Avoid dust formation.

**6.4. Reference to other sections**

Safe handling: see section 7

Disposal: see section 13

**SECTION 7: Handling and storage****7.1. Precautions for safe handling****Advice on safe handling**

Provide adequate ventilation. Use personal protection equipment. Avoid contact with skin, eyes and clothes. Do not breathe dust/fume/gas/mist/vapours/spray. Keep container tightly closed and dry.

**Advice on protection against fire and explosion**

Keep away from sources of heat (e.g. hot surfaces), sparks and open flames.

**Further information on handling**

No information available.

**7.2. Conditions for safe storage, including any incompatibilities****Requirements for storage rooms and vessels**

Recommended storage temperature: < -15 °C

**Hints on joint storage**

Do not store together with:

Food and feedingstuffs

**Further information on storage conditions**

Protect against:

Heat

Humidity

**SECTION 8: Exposure controls/personal protection****8.1. Control parameters****Additional advice on limit values**

To date, no national critical limit values exist.

**8.2. Exposure controls****Appropriate engineering controls**

Provide adequate ventilation as well as local exhaustion at critical locations.

**Protective and hygiene measures**

Work in well-ventilated zones or use proper respiratory protection. Only wear fitting, comfortable and clean protective clothing. Avoid contact with skin, eyes and clothes. Wash hands and face before breaks and after work and take a shower if necessary. When using do not eat, drink or smoke.

**Eye/face protection**

Suitable eye protection:

Eye glasses with side protection

goggles

**Hand protection**

Wear protective gloves.

Suitable material: NBR (Nitrile rubber), Butyl caoutchouc (butyl rubber)

The quality of the protective gloves resistant to chemicals must be chosen as a function of the specific working place concentration and quantity of hazardous substances. For special purposes, it is recommended to check

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the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves.

**Skin protection**

Protective clothing

**Respiratory protection**

If technical exhaust or ventilation measures are not possible or insufficient, respiratory protection must be worn.:

Self-contained respirator (breathing apparatus) (DIN EN 133)

Combination filtering device (EN 14387)

**Environmental exposure controls**

Avoid release to the environment.

**SECTION 9: Physical and chemical properties****9.1. Information on basic physical and chemical properties**

Physical state:	solid
Colour:	white
Odour:	This information is not available.
Odour threshold:	This information is not available.
pH-Value:	No data available

**Changes in the physical state**

Melting point:	No data available
Initial boiling point and boiling range:	No data available
Sublimation point:	No data available
Softening point:	No data available
Pour point:	No data available
Flash point:	No data available
Sustaining combustion:	No data available

**Explosive properties**

No data available

Lower explosion limits:	No data available
Upper explosion limits:	No data available
Ignition temperature:	No data available
Decomposition temperature:	No data available

**Oxidizing properties**

No data available

Vapour pressure:	No data available
Density:	No data available
Bulk density:	No data available
Water solubility: (at 25 °C)	1 g/L
Partition coefficient:	No data available
Viscosity / dynamic:	No data available
Viscosity / kinematic:	No data available
Vapour density:	No data available
Evaporation rate:	No data available
Solvent content:	No data available

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### 9.2. Other information

No data available

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

No data available

### 10.2. Chemical stability

The substance is chemically stable under recommended conditions of storage, use and temperature.

### 10.3. Possibility of hazardous reactions

No data available

### 10.4. Conditions to avoid

No data available

### 10.5. Incompatible materials

No data available

### 10.6. Hazardous decomposition products

Thermal decomposition can lead to the escape of irritating gases and vapours.

### Further information

No data available

## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects

#### Acute toxicity

Based on available data, the classification criteria are not met.

#### Irritation and corrosivity

Based on available data, the classification criteria are not met.

#### Sensitising effects

Based on available data, the classification criteria are not met.

#### Carcinogenic/mutagenic/toxic effects for reproduction

May damage fertility or the unborn child. (Degarelix acetate salt)

Germ cell mutagenicity: Based on available data, the classification criteria are not met.

Carcinogenicity: Based on available data, the classification criteria are not met.

#### STOT-single exposure

Based on available data, the classification criteria are not met.

#### STOT-repeated exposure

Based on available data, the classification criteria are not met.

#### Aspiration hazard

Based on available data, the classification criteria are not met.

## SECTION 12: Ecological information

### 12.1. Toxicity

The product has not been tested.

### 12.2. Persistence and degradability

The product has not been tested.

### 12.3. Bioaccumulative potential

The product has not been tested.

### 12.4. Mobility in soil

The product has not been tested.

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**12.5. Results of PBT and vPvB assessment**

The product has not been tested.

**12.6. Other adverse effects**

No information available.

**Further information**

Avoid release to the environment.

**SECTION 13: Disposal considerations****13.1. Waste treatment methods****Disposal recommendations**

Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil.

**Contaminated packaging**

Non-contaminated packages may be recycled. Handle contaminated packages in the same way as the substance itself.

**SECTION 14: Transport information****Land transport (ADR/RID)**

<b><u>14.1. UN number:</u></b>	No dangerous good in sense of this transport regulation.
<b><u>14.2. UN proper shipping name:</u></b>	No dangerous good in sense of this transport regulation.
<b><u>14.3. Transport hazard class(es):</u></b>	No dangerous good in sense of this transport regulation.
<b><u>14.4. Packing group:</u></b>	No dangerous good in sense of this transport regulation.

**Inland waterways transport (ADN)**

<b><u>14.1. UN number:</u></b>	No dangerous good in sense of this transport regulation.
<b><u>14.2. UN proper shipping name:</u></b>	No dangerous good in sense of this transport regulation.
<b><u>14.3. Transport hazard class(es):</u></b>	No dangerous good in sense of this transport regulation.
<b><u>14.4. Packing group:</u></b>	No dangerous good in sense of this transport regulation.

**Marine transport (IMDG)**

<b><u>14.1. UN number:</u></b>	No dangerous good in sense of this transport regulation.
<b><u>14.2. UN proper shipping name:</u></b>	No dangerous good in sense of this transport regulation.
<b><u>14.3. Transport hazard class(es):</u></b>	No dangerous good in sense of this transport regulation.
<b><u>14.4. Packing group:</u></b>	No dangerous good in sense of this transport regulation.

**Air transport (ICAO-TI/IATA-DGR)**

<b><u>14.1. UN number:</u></b>	No dangerous good in sense of this transport regulation.
<b><u>14.2. UN proper shipping name:</u></b>	No dangerous good in sense of this transport regulation.
<b><u>14.3. Transport hazard class(es):</u></b>	No dangerous good in sense of this transport regulation.
<b><u>14.4. Packing group:</u></b>	No dangerous good in sense of this transport regulation.

**14.5. Environmental hazards**

ENVIRONMENTALLY HAZARDOUS: no

**14.6. Special precautions for user**

No dangerous good in sense of this transport regulation.

**14.7. Transport in bulk according to Annex II of Marpol and the IBC Code**

No dangerous good in sense of this transport regulation.

**SECTION 15: Regulatory information****15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture**

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### National regulatory information

#### 15.2. Chemical safety assessment

For this substance a chemical safety assessment has not been carried out.

### SECTION 16: Other information

#### Abbreviations and acronyms

ADR: Accord européen sur le transport des marchandises dangereuses par Route  
(European Agreement concerning the International Carriage of Dangerous Goods by Road )  
RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer  
(Regulations Concerning the International Transport of Dangerous Goods by Rail )  
IMDG: International Maritime Code for Dangerous Goods  
IATA: International Air Transport Association  
IATA-DGR: Dangerous Goods Regulations by the "International Air Transport Association" (IATA)  
ICAO: International Civil Aviation Organization  
ICAO-TI: Technical Instructions by the "International Civil Aviation Organization" (ICAO)  
CAS: Chemical Abstracts Service (division of the American Chemical Society)  
GHS: Globally Harmonized System of Classification and Labelling of Chemicals  
CLP: Regulation on Classification, Labelling and Packaging of Substances and Mixtures  
ATE: Acute toxic estimate  
LC50: Lethal concentration, 50 percent  
LD50: Lethal dose, 50 percent  
EC50: Effect concentration, 50 percent  
DNEL: Derived No Effect Level  
PNEC: Predicted No Effect Concentration  
PBT: Persistent, Bioaccumulative and Toxic  
vPvB: very Persistent and very Bioaccumulative

#### Relevant H and EUH statements (number and full text)

H360 May damage fertility or the unborn child.

#### Further Information

The information is based on the present level of our knowledge. It does not, however, give assurance of product properties and establishes no contract legal rights.