

Version	Revision Date:	SDS Number:	Date of last issue: 29.03.2018
4.1	29.03.2018	13395	Date of first issue: 28.07.2017

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## SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

### 1.1 Product identifier

## ZOLADEX FOR DEPOT/IMPLANT

Details of the supplier of the safety data sheet	: ASTRAZENECA PTY LTD PO Box 131 66 Talavera Rd, North Ryde NSW 2113 AUSTRALIA +61 2 9978 3500	Emergency Telephone +44 (0) 1235 239 670
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SafetyDataSheets.AlderleyPark@astrazeneca.com

### Alternative Names

Zoladex 3.6 mg and 10 mg	
Goserelin acetate in co-polymer matrix	
CAS No.	: Not applicable

### 1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Substance/Mixture	: Zoladex 3.6 mg; Management of: (i) Prostate cancer (ii) Breast cancer (iii) Endometriosis (iv) Uterine fibroids (v) Endometrial thinning (vi) Assisted reproduction, ;, Zoladex 10.8 mg; Management of: (i) Prostate cancer (ii) Endometriosis (iii) Uterine fibroids
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## SECTION 2. HAZARDS IDENTIFICATION

### GHS Classification

Reproductive toxicity	: Category 1B
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### GHS label elements

Hazard pictograms	: 
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Signal word	: Danger
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Hazard statements	: H360 May damage fertility or the unborn child.
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Precautionary statements	: <b>Prevention:</b> P201 Obtain special instructions before use. P202 Do not handle until all safety precautions have been read and understood. P281 Use personal protective equipment as required.
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	: <b>Response:</b> P308 + P313 IF exposed or concerned: Get medical advice/attention.
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	: <b>Disposal:</b>
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Version 4.1      Revision Date: 29.03.2018      SDS Number: 13395      Date of last issue: 29.03.2018  
Date of first issue: 28.07.2017

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P501 Dispose of contents/ container to an approved waste disposal plant.

Hazardous components which must be listed on the label:

Goserelin acetate

**Other hazards which do not result in classification**

See Section 11.

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### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

**Hazardous components**

Chemical name	CAS-No.	Concentration (% w/w)
Goserelin acetate	145781-92-6	16.7 -23.1

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### SECTION 4. FIRST AID MEASURES

If inhaled : Remove patient from exposure.  
Obtain medical attention if ill effects occur.

In case of skin contact : Wash skin with soap and water.

In case of eye contact : Irrigate with eyewash solution or clean water, holding the eyelids apart, for at least 10 minutes.  
Obtain medical attention if ill effects remain.

If swallowed : Wash out mouth with water and give 200-300ml of water to drink.  
Do NOT induce vomiting as a First-Aid measure.  
Obtain medical attention if ill effects occur.

Most important symptoms and effects, both acute and delayed : Refer to sections 2 and 11  
May damage fertility or the unborn child.

Notes to physician : Symptomatic treatment and supportive therapy as indicated.  
For further detail consult the prescribing information.

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### SECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing media : water spray, foam, dry powder or CO<sub>2</sub>.

Unsuitable extinguishing media : -

Specific hazards during firefighting : If involved in a fire, it may emit noxious and toxic fumes.

Special protective equipment for firefighters : A self contained breathing apparatus and full protective clothing should be worn in fire conditions.

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Version 4.1      Revision Date: 29.03.2018      SDS Number: 13395      Date of last issue: 29.03.2018  
 Date of first issue: 28.07.2017

## SECTION 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Ensure suitable personal protection during removal of spillages.  
See Section 8.
- Environmental precautions : Prevent entry into drains, sewers or watercourses.
- Methods and materials for containment and cleaning up : Clear up spillages.  
Wash the spillage area with water.  
Transfer to a container for disposal.

## SECTION 7. HANDLING AND STORAGE

- Advice on safe handling : Avoid contact with skin and eyes.
- Conditions for safe storage : Keep only in the original container.
- Recommended storage temperature : < 25 °C

## SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Goserelin acetate	145781-92-6	TWA	0.005 mg/m <sup>3</sup>	COM; HYG

- Engineering measures** : The specific controls will depend on local circumstances and should be based on the risk assessment. Appropriate controls to reduce exposure may include engineering controls, for example ventilation, procedural controls and the use of personal protection equipment.

Prevent entry into drains, sewers or watercourses.

### Personal protective equipment

- Respiratory protection : Use an air fed hood if the risk assessment does not support the selection of other protection.
- Eye protection : Use safety glasses to protect against direct contact with the product if the risk assessment does not support the selection of other protection.
- Skin and body protection : Use impervious clothing to protect against direct contact with the product or for repeated, excessive handling use full chemical protective suit if the risk assessment does not support the selection of other protection. Use impervious protective gloves to protect against direct contact with the product. If the product is dissolved or wetted use a glove

Version	Revision Date:	SDS Number:	Date of last issue: 29.03.2018
4.1	29.03.2018	13395	Date of first issue: 28.07.2017

---

material that is resistant to the solvent/liquid.

Protective measures : Decisions about whether the use of personal protective equipment (PPE) is appropriate as part of the control strategy should be based on the workplace risk assessment and should take account of local legislative requirements for selection and use. There are multiple factors that will affect the specific requirements such as amount and concentration of the material, duration of exposure, frequency of exposure, external environmental conditions, the task, the user etc. All the information above should not be used in isolation and should be considered in the context of the workplace risk assessment on a case by case basis.

The recommended personal protective equipment (PPE) is based on preventing the potential adverse health effects from exposure to the active pharmaceutical ingredient (API). The risk of exposure to the API in the formulation/product needs to be taken into consideration.

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## SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	: depot
Colour	: white-cream
Odour	: No data available
Odour Threshold	: No data available
pH	: No data available
Melting point/range	: No data available
Initial boiling point and boiling range	: No data available
Flash point	: No data available
Evaporation rate	: No data available
Flammability (solid, gas)	: No data available
Upper explosion limit / Upper flammability limit	: No data available
Lower explosion limit / Lower flammability limit	: No data available
Vapour pressure	: No data available
Relative vapour density	: No data available

# SAFETY DATA SHEET



Version 4.1      Revision Date: 29.03.2018      SDS Number: 13395      Date of last issue: 29.03.2018  
Date of first issue: 28.07.2017

---

Relative density : No data available

Solubility(ies)  
Water solubility : No data available

Solubility in other solvents : No data available

Partition coefficient: n-octanol/water : No data available

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity  
Viscosity, dynamic : No data available

Viscosity, kinematic : No data available

Explosive properties : No data available

Oxidizing properties : No data available

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## SECTION 10. STABILITY AND REACTIVITY

Reactivity : No known reactivity hazard under normal conditions.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reactions : None known.

Conditions to avoid : No conditions producing hazardous situations known.

Incompatible materials : None known.

Hazardous decomposition products : No hazardous decomposition products are known.

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## SECTION 11. TOXICOLOGICAL INFORMATION

### 11.1 Acute toxicity

Not classified based on available information.

#### **Components:**

##### **Goserelin acetate:**

Acute oral toxicity : Remarks: Low acute toxicity.

Acute inhalation toxicity : Remarks: Low acute toxicity.

Acute dermal toxicity : Remarks: Low acute toxicity.

Version 4.1      Revision Date: 29.03.2018      SDS Number: 13395      Date of last issue: 29.03.2018  
Date of first issue: 28.07.2017

---

## 11.2 Skin corrosion/irritation

Not classified based on available information.

### Components:

#### **Goserelin acetate:**

Remarks: Unlikely to cause skin irritation.

## 11.3 Serious eye damage/eye irritation

Not classified based on available information.

### Components:

#### **Goserelin acetate:**

Remarks: Unlikely to cause eye irritation.

## 11.4 Respiratory or skin sensitisation

### **Skin sensitisation**

Not classified based on available information.

### **Respiratory sensitisation**

Not classified based on available information.

### Components:

#### **Goserelin acetate:**

Remarks: Unlikely to cause skin sensitisation.

## Chronic toxicity

### 11.5 Germ cell mutagenicity

Not classified based on available information.

### Components:

#### **Goserelin acetate:**

Germ cell mutagenicity - Assessment : There is no evidence of genotoxic potential in in vitro and in vivo tests.

### 11.6 Carcinogenicity

Not classified based on available information.

### Components:

#### **Goserelin acetate:**

Carcinogenicity - Assessment : Studies in animals have shown that repeated doses produce tumors in rats (benign)., The relevance to humans has not been established.

### 11.7 Reproductive toxicity

May damage fertility or the unborn child.

Version	Revision Date:	SDS Number:	Date of last issue: 29.03.2018
4.1	29.03.2018	13395	Date of first issue: 28.07.2017

---

**Components:****Goserelin acetate:**

Reproductive toxicity - Assessment : Clear evidence of adverse effects on sexual function and fertility, based on animal experiments., Repeated exposure produces adverse effects on the menstrual cycle in women causing suppression of ovulation, may cause interaction with maintenance of pregnancy, and produces a reduction in fertility in men.

**11.8 STOT - single exposure**

Not classified based on available information.

**Components:****Goserelin acetate:**

Remarks: No specific effects reported.

**11.9 STOT - repeated exposure**

Not classified based on available information.

**Components:****Goserelin acetate:**

Remarks: Interacts with hormonal system and may cause adverse effects including decreased libido, hot flushes, hyperhidrosis, acne, paraesthesia and skin rashes.

**11.10 Aspiration toxicity**

Not classified based on available information.

**Components:****Goserelin acetate:**

No information available.

**Further information****Product:**

Remarks: This health hazard assessment is based on a consideration of the composition of this product.

Information refers to Goserelin acetate.

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**SECTION 12. ECOLOGICAL INFORMATION****Ecotoxicity****Product:****Ecotoxicology Assessment**

Chronic aquatic toxicity : This product has no known ecotoxicological effects.  
Remarks: The following information refers to active ingredient: Goserelin acetate.

Version 4.1      Revision Date: 29.03.2018      SDS Number: 13395      Date of last issue: 29.03.2018  
Date of first issue: 28.07.2017

---

**Components:****Goserelin acetate:**

Toxicity to fish : Remarks: No information available.

**Persistence and degradability****Components:****Goserelin acetate:**

Biodegradability : Inoculum: activated sludge  
Concentration: 50 mg/l  
Result: Readily biodegradable.  
Biodegradation: 92 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301F

Inoculum: activated sludge  
Concentration: 100 mg/l  
Result: Readily biodegradable.  
Biodegradation: 72 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301F

**Bioaccumulative potential****Components:****Goserelin acetate:**

Bioaccumulation : Remarks: No information available.

**Mobility in soil****Components:****Goserelin acetate:**

Mobility : Remarks: No information available.

Distribution among environmental compartments : Remarks: No information available.

**Other adverse effects**

No data available

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**SECTION 13. DISPOSAL CONSIDERATIONS****Disposal methods**

Waste from residues : Disposal should be in accordance with local, state or national legislation.  
Waste, even small quantities, should never be poured down drains, sewers or water courses.  
Dispose of contents/ container to an approved incineration



# SAFETY DATA SHEET



Version 4.1      Revision Date: 29.03.2018      SDS Number: 13395      Date of last issue: 29.03.2018  
Date of first issue: 28.07.2017

---

plant.

Contaminated packaging : Empty container will retain product residue. Observe all hazard precautions.

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## SECTION 14. TRANSPORT INFORMATION

Not classified as dangerous in the meaning of transport regulations.

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## SECTION 15. REGULATORY INFORMATION

### **Safety, health and environmental regulations/legislation specific for the substance or mixture**

In order to comply with legal duties it is necessary to consult local and national legislation.

Prohibition/Licensing Requirements : There is no applicable prohibition or notification/licensing requirements, including for carcinogens under Commonwealth, State or Territory legislation.

### **The components of this product are reported in the following inventories:**

REACH : Not listed

DSL : This product contains the following components that are not on the Canadian DSL nor NDSL.

Goserelin acetate 145781-92-6

AICS : Not listed

ENCS : Not listed

ISHL : Not listed

IECSC : Not listed

TCSI : Not listed

TSCA : Not On TSCA Inventory

Version	Revision Date:	SDS Number:	Date of last issue: 29.03.2018
4.1	29.03.2018	13395	Date of first issue: 28.07.2017

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**SECTION 16. OTHER INFORMATION****Full text of other abbreviations**

AICS - Australian Inventory of Chemical Substances; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; CPR - Controlled Products Regulations; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

**Further information**

Revision Date	:	29.03.2018
Other information	:	New significant SHE information:, 8. New Occupational Exposure Limit Value, Minor changes:, 3, 11
Date format	:	dd.mm.yyyy

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