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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      Emergency Telephone  
 PO Box 131      +44 (0) 1235 239 670  
 Alma Road, North Ryde  
 NSW 2113  
 AUSTRALIA  
 +61 2 9978 3500  
 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

### GHS label elements

Hazard pictograms : 

Signal word : Danger

Hazard statements : H360 May damage fertility or the unborn child.

Precautionary statements : **Prevention:**  
 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.  
**Response:**  
 P308 + P313 IF exposed or concerned: Get medical advice/attention.  
**Disposal:**

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

## Other hazards which do not result in classification

See Section 11.

## SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

### Hazardous components

Chemical name	CAS-No.	Concentration (% w/w)
Goserelin acetate	145781-92-6	>= 20 - < 30

## 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.

## SECTION 5. FIREFIGHTING MEASURES

- Suitable extinguishing media : water spray, foam, dry powder or CO2.
- 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.

## SECTION 6. ACCIDENTAL RELEASE MEASURES

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- 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	0.0025 mg/m3	COM

- 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 material that is resistant to the solvent/liquid.

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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	: No data available
Lower explosion limit	: No data available
Vapour pressure	: No data available
Relative vapour density	: No data available
Relative density	: No data available
Solubility(ies) Water solubility	: No data available

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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

### 11.1.1 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.

### 11.1.2 Skin corrosion/irritation

Not classified based on available information.

#### **Components:**

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

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Remarks: Unlikely to cause skin irritation.

#### 11.1.3 Serious eye damage/eye irritation

Not classified based on available information.

##### Components:

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

Remarks: Unlikely to cause eye irritation.

#### 11.1.4 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.

#### 11.1.5 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.

#### 11.1.6 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.

#### 11.1.7 Reproductive toxicity

May damage fertility or the unborn child.

##### 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.

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## 11.1.8 STOT - single exposure

Not classified based on available information.

### Components:

#### **Goserelin acetate:**

Remarks: No specific effects reported.

## 11.1.9 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.

## 11.1.10 Aspiration toxicity

Not classified based on available information.

### Components:

#### **Goserelin acetate:**

No information available.

### **Further information**

#### Product:

Remarks: The following 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.

### Components:

#### **Goserelin acetate:**

Toxicity to fish                        :    Remarks: No information available.

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**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 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

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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; COM - In-house occupational exposure limit; CPR - Controlled Products Regulations; 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 -

