# SAFETY DATA SHEET

## 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

**Product identifier**

# ZOLADEX FOR DEPOT/IMPLANT

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**Alternative Names**
Zoladex 3.6 mg and 10 mg
Goserelin acetate in co-polymer matrix

CAS No. : Not applicable
Use : 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

## 2. HAZARDS IDENTIFICATION

### Classification of the substance or mixture

**Classification UN GHS**

| Hazard class | Category | Hazard statements |
|---|---|---|
| Reproductive toxicity | 1B | H360<br># Refer to Section 16 'Other Information' |

**Label elements**

**Signal word**
Danger

**Hazard statements**

H360 : May damage fertility.

**Precautionary statements**

P201 Obtain special instructions before use.

P281 Use personal protective equipment as required.

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

| | | |
|---|---|---|
| P501 | : | Dispose of contents/ container to an approved incineration plant. |

**Other hazards**
See Section 11.

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

**Mixture:**

| Component | % | CAS No. | | |
|---|---|---|---|---|
| Goserelin acetate | 16,7 - 23,1 | 145781-92-6 | | |
| | **Hazard class** # | | **Category** | **Hazard statements** # |
| | Reproductive toxicity | | 1B | H360 |

# Refer to Section 16 'Other Information'

## 4. FIRST-AID MEASURES

**Description of first aid measures**

| | | |
|---|---|---|
| Inhalation | : | Remove patient from exposure. Obtain medical attention if ill effects occur. |
| Skin Contact | : | Wash skin with soap and water. |
| 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. |
| Ingestion | : | 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

**Indication of any immediate medical attention and special treatment needed**
Symptomatic treatment and supportive therapy as indicated. For further detail consult the prescribing information.

## 5. FIRE-FIGHTING MEASURES

| | | |
|---|---|---|
| Extinguishing Media (suitable) | : | water spray, foam, dry powder or CO2. |
| Extinguishing Media (unsuitable) | : | - |
| Special hazards arising from the substance or mixture | : | If involved in a fire, it may emit noxious and toxic fumes. |
| Special protective actions for fire-fighters | : | A self contained breathing apparatus and full protective clothing should be worn in fire conditions. |

## 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 material for containment and cleaning up | : | Clear up spillages. Wash the spillage area with water. Transfer to a container for disposal. |

## 7. HANDLING AND STORAGE

| | | |
|---|---|---|
| Precautions for safe handling | : | Avoid contact with skin and eyes. |

| | | |
|---|---|---|
| Conditions for safe storage, including any incompatibilities | : | Keep only in the original container.<br><br>Storage temperature : < 25 °C |
| Specific end use(s) | : | Not applicable, refer to Section 1 |

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

**Control parameters**

**Occupational Exposure Limit Value**

| Components | Value | Control parameters | Comments |
|---|---|---|---|
| Goserelin acetate | 0,0025 mg/m3 | LTEL 8hr TWA | COM |

**Exposure Controls**
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.
**Occupational exposure controls**
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.
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.
The information below should not be used in isolation and should be considered in the context of the workplace risk assessment on a case by case basis.

**Respiratory protection**
Use an air fed hood if the risk assessment does not support the selection of other protection.

**Skin 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.

**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.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

**Information on basic physical and chemical properties**

| | | |
|---|---|---|
| Form | : | depot |
| Colour | : | white-cream |

**Other information**

**No other data available**

## 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. |

## 11. TOXICOLOGICAL INFORMATION

The following health hazard assessment is based on a consideration of the composition of this product.

| | | |
|---|---|---|
| Inhalation | : | Unlikely route of exposure. |
| Skin Contact | : | Unlikely to cause skin irritation. |
| Eye Contact | : | Unlikely to cause eye irritation. |
| Ingestion | : | The acute toxicity via any route of exposure relevant for the workplace is low. |
| Specific Target Organ Toxicity (STOT) | : | **Single exposure**<br>No specific effects reported.<br><br>**Repeated exposure**<br>Interacts with hormonal system and may cause adverse effects including decreased libido, hot flushes, hyperhidrosis, acne, paraesthesia and skin rashes. |
| Sensitisation | : | Unlikely to cause skin sensitisation. |
| Carcinogenicity | : | Studies in animals have shown that repeated doses produce tumors in rats (benign).<br>The relevance to humans has not been established. |
| Mutagenicity | : | There is no evidence of genotoxic potential in in vitro and in vivo tests. |
| Reproductive toxicity | : | May damage fertility.<br>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. |

## 12. ECOLOGICAL INFORMATION

No information on this formulation. The following information refers to active ingredient:

| | | |
|---|---|---|
| Toxicity | : | No information available. |
| Effect on Effluent Treatment | : | No information available. |
| Persistence and degradability | : | Biodegradability (OECD 301F) 92% (50mg/l), 72% (100mg/l). The substance is substantially biodegradable in water. Biodegradability adapted activated sludge 33% (100mg/l). |
| Bioaccumulative potential | : | No information available. |
| Mobility in soil | : | No information available. |

Other adverse effects : No information available.

## 13. DISPOSAL CONSIDERATIONS

Waste treatment methods : Disposal should be in accordance with local, state or national legislation. This material and/or its container must be disposed of as hazardous waste. Normal waste disposal is via incineration operated by an accredited disposal contractor.

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

## 14. TRANSPORT INFORMATION

NOT RESTRICTED FOR TRANSPORT

## 15. REGULATORY INFORMATION

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

## 16. OTHER INFORMATION

Hazard statements H360 : May damage fertility.

The following sections contain revisions or new statements :

New significant SHE information:
11. Ingestion
11. Specific Target Organ Toxicity (STOT): Repeated exposure

Minor changes:, 9, 11

## GLOSSARY

| | | |
|---|---|---|
| COM | : | In-house occupational exposure limit |
| LTEL | : | Long-term exposure limit (8 hour TWA (time-weighted average)) |
| STEL | : | Short-term exposure limit (15-minute TWA (time-weighted average)) |
| TLV | : | Threshold Limit Value (ACGIH) |
| TLV-C | : | Threshold Limit Value - Ceiling limit (ACGIH) |
| HYG | : | An in-house analytical method for occupational exposure monitoring is available |
| Sk | : | Can be absorbed through skin, thus contributing to systemic effects |
| Sen | : | Capable of causing respiratory sensitisation |

This Glossary is applicable to Substances for which Hazardous Ingredients/Occupational Exposure Limits are assigned.