SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

1.1 Product identifier

FASLODEX SOLUTION FOR INJECTION
Details of the supplier of the safety data sheet: ASTRazeneca Pty Ltd
PO Box 131
Alma Road, North Ryde
NSW 2113
AUSTRALIA
+61 2 9978 3500

Emergency Telephone +44 (0) 1235 239 670
SafetyDataSheets.AlderleyPark@astrazeneca.com

Alternative Names
ICI 182,780 long acting injection
Faslodex vials/pre-filled syringe for injection
CAS No.: Not applicable

1.2 Relevant identified uses of the substance or mixture and uses advised against
Use of the Substance/Mixture: Treatment of advanced breast cancer in postmenopausal women previously treated with hormonal therapy.

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification
Flammable liquids: Category 3
Acute toxicity (Oral): Category 4
Reproductive toxicity: Category 1B
Effects on or via lactation:
Chronic aquatic toxicity: Category 1

GHS label elements
Hazard pictograms:

Signal word: Danger
Hazard statements:
H226 Flammable liquid and vapour.
H302 Harmful if swallowed.
H360 May damage fertility or the unborn child.
H362 May cause harm to breast-fed children.
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements:
Prevention:
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P210 Keep away from heat/sparks/open flames/hot surfaces.
No smoking.
P233 Keep container tightly closed.
P240 Ground/bond container and receiving equipment.
P241 Use explosion-proof electrical/ventilating/lighting/equipment.
P242 Use only non-sparking tools.
P243 Take precautionary measures against static discharge.
P264 Wash skin thoroughly after handling.
P273 Avoid release to the environment.
P280 Wear protective gloves/eye protection/face protection.
P281 Use personal protective equipment as required.

Response:
P301 + P312 + P330 IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell. Rinse mouth.
P303 + P361 + P353 IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.
P308 + P313 IF exposed or concerned: Get medical advice/attention.
P391 Collect spillage.

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

Other hazards which do not result in classification
None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Hazardous components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzyl benzoate</td>
<td>120-51-4</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td>Ethanol</td>
<td>64-17-5</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td>Benzyl alcohol</td>
<td>100-51-6</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td>Fulvestrant</td>
<td>129453-61-8</td>
<td>&gt;= 1 - &lt; 10</td>
</tr>
</tbody>
</table>

SECTION 4. FIRST AID MEASURES

If inhaled : Remove patient from exposure, keep warm and at rest. Obtain medical attention.

In case of skin contact : Remove contaminated clothing. Wash skin with water. If symptoms (irritation or blistering) occur obtain medical attention.
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 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.

Most important symptoms and effects, both acute and delayed: Refer to sections 2 and 11
- Harmful if swallowed.
- May damage fertility or the unborn child.
- May cause harm to breast-fed children.

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

SECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing media: foam, CO2 or dry powder. Water spray should be used to cool containers.

Unsuitable extinguishing media: Do not use water jet.

Specific hazards during firefighting: Flammable liquid and vapour. The vapour is heavier than air and may travel a considerable distance to a source of ignition and flashback. Combustion will evolve toxic vapours.

Special protective equipment for firefighters: A self contained breathing apparatus and suitable protective clothing should be worn in fire conditions. Prevent fire extinguishing water from contaminating surface water or the ground water system.

SECTION 6. ACCIDENTAL RELEASE MEASURES


Environmental precautions: Prevent entry into drains, sewers or watercourses. Collect spillage.

Methods and materials for containment and cleaning up: Absorb spillages onto sand, earth or any suitable adsorbent material. Do not adsorb onto sawdust or other combustible materials. Transfer to a container for disposal. Wash the spillage area with water. Avoid release to the environment. See section 13.

SECTION 7. HANDLING AND STORAGE
Advice on safe handling: Avoid contact with skin and eyes. Avoid inhalation of vapour/mist. Take precautionary measures against static discharges.

Conditions for safe storage: Keep container tightly closed, in a cool, well ventilated place. Keep away from sources of ignition - No Smoking. Protect from light.

Recommended storage temperature: 2 - 8 °C

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethanol</td>
<td>64-17-5</td>
<td>TWA</td>
<td>1,000 ppm / 1,880 mg/m³</td>
<td>AU OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL</td>
<td>1,000 ppm</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Fulvestrant</td>
<td>129453-61-8</td>
<td>TWA</td>
<td>0.001 mg/m³</td>
<td>COM; HYG</td>
</tr>
</tbody>
</table>

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. See Section 6 for environmental precautions.

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 liquid 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 liquid or for repeated, excessive handling use full chemical protective suit if the risk assessment does not support the selection of other protection. Use chemical protective gloves with a permeation time greater than the activity duration. Take note of the information given by the PPE producer/supplier concerning permeability and breakthrough times and special workplace conditions.

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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>liquid</td>
</tr>
<tr>
<td>Colour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour</td>
<td>ethereal</td>
</tr>
<tr>
<td>Odour Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/range</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>29 °C</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Upper explosion limit</td>
<td>3.5 %(V)</td>
</tr>
<tr>
<td>Lower explosion limit</td>
<td>19 %(V)</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapour density</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td></td>
</tr>
<tr>
<td>Water solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility in other solvents</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>No data available</td>
</tr>
</tbody>
</table>
### Auto-ignition temperature
- Temperature: 365 °C

### Decomposition temperature
- 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

### 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.

### SECTION 11. TOXICOLOGICAL INFORMATION

#### 11.1.1 Acute toxicity
- Harmful if swallowed.

**Product:**

- **Acute oral toxicity:**
  - Acute toxicity estimate: 2,000 mg/kg
  - Method: Calculation method
  - Remarks: May cause effects as described under single exposure. (STOT)

- **Acute inhalation toxicity:**
  - Acute toxicity estimate: > 20 mg/l
  - Exposure time: 4 H
  - Test atmosphere: vapour
  - Method: Calculation method
  - Remarks: May cause effects as described under single exposure. (STOT)

- **Acute dermal toxicity:**
  - Remarks: May cause effects as described under repeated exposure. (STOT)
Components:
Fulvestrant:
- Acute oral toxicity: Remarks: Low acute oral toxicity.
- Acute inhalation toxicity: Remarks: May cause effects as described under repeated exposure (STOT).
- Acute dermal toxicity: Remarks: No information available.

11.1.2 Skin corrosion/irritation
Not classified based on available information.

Product:
Remarks: May cause skin irritation.

Components:
Benzyl benzoate:
Remarks: May cause skin irritation.

Fulvestrant:
Result: Mild skin irritation

11.1.3 Serious eye damage/eye irritation
Not classified based on available information.

Product:
Remarks: The vapour and liquid are irritant.
May cause strong stinging and burning sensation.
Permanent damage is unlikely.

Components:
Benzyl benzoate:
Remarks: May cause eye irritation.

Benzyl alcohol:
Remarks: The vapour and liquid are irritant.

Fulvestrant:
Remarks: May cause eye irritation.
Unlikely to be a severe irritant to the eye.

11.1.4 Respiratory or skin sensitisation
Skin sensitisation
Not classified based on available information.
Respiratory sensitisation
Not classified based on available information.
**Product:**
Remarks: Rare cases of skin sensitisation have been reported.

**Components:**

**Benzyl benzoate:**
Remarks: Repeated and/or prolonged contact may cause skin sensitisation.

**Fulvestrant:**
Remarks: Unlikely to cause skin sensitisation.

11.1.5 **Germ cell mutagenicity**
Not classified based on available information.

**Components:**

**Fulvestrant:**
Germ cell mutagenicity - Assessment: The substance is not considered to be genotoxic.

11.1.6 **Carcinogenicity**
Not classified based on available information.

**Components:**

**Fulvestrant:**
Carcinogenicity - Assessment: A lifetime study in animals has shown that repeated doses produce benign tumours of the ovaries and testes in rats. These effects are related to the compound’s hormonal activity.

11.1.7 **Reproductive toxicity**
May damage fertility or the unborn child.
May cause harm to breast-fed children.

**Components:**

**Fulvestrant:**
Reproductive toxicity - Assessment: Clear evidence of adverse effects on development, based on animal experiments. Some evidence of adverse effects on sexual function and fertility, based on animal experiments. Repeated exposure may produce adverse effects on the reproductive systems of men and women. Studies in animals have shown that low doses produce embryo/foetotoxic effects in the absence of maternal toxicity, (including embryolethality). Effects on or via lactation

11.1.8 **STOT - single exposure**
Not classified based on available information.
Components:

Benzyl alcohol:
Remarks: May cause irritation to the upper respiratory tract. Ingestion may cause irritation of the gastrointestinal tract. The vapour has anaesthetic properties and when inhaled at concentrations above the occupational exposure limit it may cause headache, fatigue, dizziness, incoordination and loss of consciousness.

Fulvestrant:
Remarks: No specific effects reported.

11.1.9 STOT - repeated exposure
Not classified based on available information.

Components:

Benzyl alcohol:
Remarks: Repeated and/or prolonged contact with the skin may have a degreasing action and cause dermatitis.

Fulvestrant:
Exposure routes: Oral
Remarks: An ingestion study in animals has shown that high doses produce adverse effects on the heart.

11.1.10 Aspiration toxicity
Not classified based on available information.

Components:

Fulvestrant:
No information available.

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

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Product:

Ecotoxicology Assessment
Chronic aquatic toxicity: Very toxic to aquatic life with long lasting effects.
Remarks: This environmental hazard assessment is based on information available on the components of the formulation. Information refers to Fulvestrant
Components:

Fulvestrant:
Toxicity to algae: NOEC (Pseudokirchneriella subcapitata (green algae)): 0.047 mg/l
Exposure time: 72 H
Method: OECD Test Guideline 201
Remarks: No toxicity at the limit of solubility

Toxicity to fish (Chronic toxicity): NOEC (Pimephales promelas (fathead minnow)): 0.0000057 mg/l
Exposure time: 42 d

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity): NOEC (Daphnia magna (Water flea)): 0.01 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211
Remarks: No toxicity at the limit of solubility

M-Factor (Chronic aquatic toxicity): 10,000

Toxicity to bacteria: IC50 (Sewage sludge organisms): > 100 mg/l
Exposure time: 3 H
Method: OECD Test Guideline 209

Ecotoxicology Assessment
Chronic aquatic toxicity: Very toxic to aquatic life with long lasting effects.

Persistence and degradability

Components:

Fulvestrant:
Biodegradability: aerobic
Inoculum: activated sludge
Concentration: 100 mg/l
Biodegradation: < 5 %
Exposure time: 28 d
Method: OECD Test Guideline 301F
Remarks: Not rapidly degradable.

Bioaccumulative potential

Components:

Fulvestrant:
Bioaccumulation: Species: Oncorhynchus mykiss (rainbow trout)
Bioconcentration factor (BCF): 355
Concentration: 0.0001 mg/l
Method: OECD Test Guideline 305

Species: Oncorhynchus mykiss (rainbow trout)
Bioconcentration factor (BCF): 357
Concentration: 0.001 mg/l
Method: OECD Test Guideline 305

Remarks: The substance has low potential for bioaccumulation.

Mobility in soil

Components:

Fulvestrant:
Mobility:
分布 among environmental compartments
Remarks: The substance is essentially insoluble in water.
Remarks: No information available.

Other adverse effects
No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods
Waste from residues:
Disposal should be in accordance with local, state or national legislation.
Solvent residues must not be allowed to enter drains, sewers or watercourses or to contaminate the ground.
Dispose of contents/container to an approved incineration plant.
Large volumes may be suitable for redistillation by solvent contractors.

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

SECTION 14. TRANSPORT INFORMATION

ICAO/IATA

UN No. 1993
Proper Shipping Name: Flammable liquid, n.o.s. (ETHANOL, FULVESTRANT)
Class 3
Packing Group III

IMO/IMDG

UN No. 1993
Proper Shipping Name: FLAMMABLE LIQUID, N.O.S. (ETHANOL, FULVESTRANT)
SAFETY DATA SHEET

Class : 3
Packing Group : III
Marine pollutant : Marine pollutant

ADR

UN No. : 1993
Proper Shipping Name : FLAMMABLE LIQUID, N.O.S. (ETHANOL, FULVESTRANT)
Class : 3
Label(s) : 3
Packing Group : III
Environmental hazards : Environmentally hazardous

SECTION 15. REGULATORY INFORMATION

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

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.

Fulvestrant : 129453-61-8

AICS : Not listed
ENCS : Not listed
ISHL : Not listed
IECSC : Not listed
TCSI : Not listed
TSCA : Not On TSCA Inventory

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 - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HYG - Analytical method for occupational exposure monitoring; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; 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; LC50 - Lethal Concentration to 50% of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); 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; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; (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; Sen – Capable of causing respiratory sensitization; Sk – Can be absorbed through skin, thus contributing to systemic effects; STEL - Short-term exposure limit 15-minutes time-weighted average; TLV – Threshold Limit Value (ACGIH); TLV-C – Threshold Limit Value Ceiling limit (ACGIH); TSCA - Toxic Substances Control Act (United States); TWA – Long-term exposure limit 8h time-weighted average; 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

Other information: The Safety Data Sheet has been updated to the SAP EH&S Standard template., This update affects all Sections of the Safety Data Sheet., New significant SHE information.; 2. New classification, 12. Ecological information, Minor changes.; 5, 6, 8, 11, 13

Date format: dd.mm.yyyy

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

AU / EN