

SAFETY DATA SHEET



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

Product identifier

FASLODEX SOLUTION FOR INJECTION

Details of the supplier of the safety data sheet : ASTRAZENECA
P.O. Box 15437
Wilmington, DE 19850-5437
USA

Phone (24 hr.) Medical :
(800) 236-9933
(24 hr.) Chemical / Spill Emergency:
INFOTRAC - (800) 535-5053

SafetyDataSheets.AlderleyPark@astrazeneca.com

Alternative Names

Faslodex® vials/pre-filled syringes for injection

CAS No. : Not applicable
Use : Treatment of advanced breast cancer in postmenopausal women previously treated with hormonal therapy.

2. HAZARDS IDENTIFICATION

Classification of the substance or mixture

Classification UN GHS		
Hazard class	Category	Hazard Statements
Flammable liquids	3	H225
Acute toxicity	4	H302
Reproductive toxicity	1B	H360
Effects on or via lactation		H362
Chronic aquatic toxicity	2	H411
		# Refer to Section 16 'Other Information'

Label elements

Signal Word

Danger



Hazard Statements

H225 : Highly flammable liquid and vapor.
H302 : Harmful if swallowed.
H360 : May damage the unborn child. Suspected of damaging fertility.
H362 : May cause harm to breast-fed children.
H411 : Toxic to aquatic life with long lasting effects.

Precautionary Statements

P233	Keep container tightly closed.
P240	Ground/bond container and receiving equipment.
P280	Wear protective gloves/ protective clothing/ eye protection/ face protection.
P303 + P361 + P353	: IF ON SKIN (or hair): Remove/ Take off immediately all contaminated clothing. Rinse skin with water/ shower.
P403 + P235	: Store in a well-ventilated place. Keep cool.
P501	: Dispose of contents/ container to an approved incineration plant.

Other hazards

See Section 11.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Mixture:

Component	%	CAS No.		
Fulvestrant	5	129453-61-8		
		Hazard class #	Category	Hazard Statements #
		Reproductive toxicant	1B	H360
		Effects on or via lactation		H362
		Chronic aquatic toxicity	1	H410
Component	%	CAS No.		
Ethanol	10	64-17-5		
		Hazard class #	Category	Hazard Statements #
		Flammable liquids	2	H225
Component	%	CAS No.		
Benzyl alcohol	10	100-51-6		
		Hazard class #	Category	Hazard Statements #
		Acute toxicity	4	H302
		Acute toxicity	4	H332
Component	%	CAS No.		
Benzyl benzoate	15	120-51-4		
		Hazard class #	Category	Hazard Statements #
		Acute toxicity	4	H302
		Chronic aquatic toxicity	2	H411

Refer to Section 16 'Other Information'

4. FIRST AID MEASURES

Description of first aid measures

- Inhalation : Remove patient from exposure, keep warm and at rest. Obtain medical attention.
- Skin Contact : Remove contaminated clothing. Wash skin with water. If symptoms (irritation or blistering) occur obtain medical attention.
- Eye Contact : Irrigate with eyewash solution or clean water, holding the eyelids apart, for at least 10 minutes. Obtain medical attention.
- 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.

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) : Foam, CO₂ or dry chemical. Water spray should be used to cool containers.

- Extinguishing Media (unsuitable) : Do not use water jet.
- Special hazards arising from the substance or mixture : Flammable. The vapor is heavier than air and may travel a considerable distance to a source of ignition and flashback. Combustion will evolve toxic vapors.
- Special protective actions for fire-fighters : A self contained breathing apparatus and suitable 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. Eliminate sources of ignition.
- Environmental Precautions : Prevent entry into drains, sewers or watercourses.
- Methods and material 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.

7. HANDLING AND STORAGE

- Precautions for safe handling : Avoid contact with skin and eyes. Avoid inhalation of vapour/mist. Take precautionary measures against static discharges.
- Conditions for safe storage, including any incompatibilities : Keep container tightly closed, in a cool, well ventilated place. Keep away from sources of ignition - No Smoking. Protect from light.
Storage temperature : 36 - 46 °F
- Specific end use(s) : Not applicable, refer to Section 1

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Occupational Exposure Limit Value

Ingredients	Value	Control parameters	Comments
Fulvestrant	0.001 mg/m3	TWA	COM
Ethanol			

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

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. 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.

Respiratory protection

As necessary, use NIOSH approved respiratory protection device consistent with the work place risk assessment. Consult a qualified safety and health professional for additional guidance, as needed.

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 liquid 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	:	liquid
Odor	:	ethereal
Flash Point	:	84 °F
Flammable Limits	:	19 %(V)
Flammable Limits (Upper)	:	3.5 %(V)
Auto Ignition Temperature	:	689 °F

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	:	May cause effects as described under single exposure.(STOT)
Skin Contact	:	May cause skin irritation. May cause effects as described under repeated exposure.(STOT)
Eye Contact	:	The vapor and liquid are irritant. May cause strong stinging and burning sensation. Permanent damage is unlikely.
Ingestion	:	Harmful if swallowed. May cause effects as described under single exposure.(STOT)
Specific Target Organ Toxicity (STOT)	:	Single exposure May cause irritation to the upper respiratory tract., Ingestion may cause irritation of the gastrointestinal tract., The vapor has anesthetic properties and when inhaled at concentrations above the occupational exposure limit it may cause headache, fatigue, dizziness, incoordination and loss of consciousness.

Repeated exposure

May cause adverse effects on the heart., Repeated and/or prolonged contact with the skin may have a degreasing action and cause dermatitis.

- Sensitization : May cause skin sensitization.
- Carcinogenicity : A lifetime study in animals has shown that repeated doses produce benign tumours of the ovaries and testes in rats.
- Mutagenicity : This material is not considered to be genotoxic.
- Reproductive toxicity : A study in animals has shown that repeated doses produce embryo/foetotoxic effects in the absence of maternal toxicity. May damage the unborn child. Suspected of damaging fertility. May cause harm to breast-fed children. Repeated exposure may produce adverse effects on the reproductive systems of men and women.

12. ECOLOGICAL INFORMATION

Very toxic to aquatic life with long lasting effects. There is no data available for this product. The following information refers to : Fulvestrant

- Toxicity : EC50 Pseudokirchneriella subcapitata (green algae) 72 H 0.047 mg/l (OECD 201)
NOEC Daphnia magna (Water flea) 21 d 0.010 mg/l
- Effect on Effluent Treatment : EC50 respiration inhibition of activated sludge > 100 mg/l
- Persistence and degradability : Not rapidly degradable.
- Bioaccumulative potential : The substance has low potential for bioaccumulation.
- Mobility in soil : The substance is essentially insoluble in water.
- Other adverse effects : No information available.

13. DISPOSAL CONSIDERATIONS

- Waste treatment methods : 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. Normal disposal is via incineration operated by an accredited disposal contractor.
- Contaminated Packaging : Empty container will retain residue. Observe all hazard precautions.

14. TRANSPORT INFORMATION

ICAO/IATA

- UN No. : 1170
- Proper Shipping Name : Ethanol solution
- Class : 3
- Packing Group : III

IMO/IMDG

UN No. : 1170
 Proper Shipping Name : ETHANOL SOLUTION
 Class : 3
 Marine pollutant : Marine pollutant
 Packing Group : III

DOT (Department of Transport)

UN No. : 1170
 Proper Shipping Name : Ethanol solutions
 Class : 3
 Packing Group : III

RESTRICTED FOR TRANSPORT

15. REGULATORY INFORMATION**Safety, health and environmental regulations/legislation specific for the substance or mixture**

TSCA (Toxic Substances Control Act) Regulations, 40 CFR 710: This product is a drug and is exempt from TSCA regulation when manufactured, processed or distributed in commerce for use as a drug. CERCLA and SARA Regulations (40 CFR 302,355,370 and 372): This product does not contain any chemicals subject to applicable reporting requirements. Other Determined Regulations: California Proposition 65: This product does not contain a listed chemical. Discarded product is a hazardous waste, No. D001, under RCRA, 40 CFR 261.21.

16. OTHER INFORMATION

The following sections contain revisions or new statements :

The Safety Data Sheet has been updated to adhere to Globally Harmonized System of Classification and Labelling of Chemicals (GHS)., This update affects most Sections of the Safety Data Sheet.

This Safety Data Sheet was prepared in accordance with Hazard Communication Standard (HCS) (29 CFR 1910.1200(g)).

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 sensitization

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

The information contained herein is based on data considered accurate and is offered solely for information, consideration and investigation. Company extends no warranties, makes no representations and assumes no responsibility as to the accuracy, completeness or suitability of this data for any third party use. The data on this Safety Data Sheet relates only to this product and does not relate to use with any other material or in any process. All chemical products should only be used by, or under the direction of, technically qualified personnel who are aware of the hazards involved and the necessity for reasonable care in handling. Hazard communication regulations require that employees must be trained on how to use a Safety Data Sheet as a source of hazard information.