



MATERIAL SAFETY DATA SHEET

1. PRODUCT AND COMPANY IDENTIFICATION

Name
FASLODEX®

Alternative Names
Faslodex® vials for injection

Address / Phone Number : AstraZeneca
PO BOX 15437
Wilmington, Delaware 19850-5437
Phone (24 hr.) Medical : (800) 236-9933
Chemtrec : (800) 424-9300

2. COMPOSITION/INFORMATION ON INGREDIENTS

Contains: castor oil 60% w/v

CAS No. : None assigned for the product
Use : Treatment of advanced breast cancer in postmenopausal women previously treated with hormonal therapy.

HAZARDOUS INGREDIENT(S)	%	CAS No.
Fulvestrant		129453-61-8
Ethanol B.P.		64-17-5
Benzyl alcohol		100-51-6
Benzyl benzoate		120-51-4

3. HAZARDS IDENTIFICATION

Form : vials, pre-filled syringe
Odor : ethereal

As a result of the physical presentation of the product, the risk to health in the normal handling of the product is expected to be low. Flammable.

4. FIRST AID MEASURES

- Inhalation : Remove patient from exposure, keep warm and at rest. Oxygen may be beneficial if breathing is laboured or patient is cyanotic. Apply artificial respiration if breathing has ceased or shows signs of failing. Obtain immediate 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 15 minutes. Obtain medical attention.
- Ingestion : Wash out mouth with water and give 200-300 ml of water to drink. Obtain immediate medical attention.

Note to Physicians

Symptomatic treatment and supportive therapy as indicated. For further detail consult the prescribing information.

5. FIRE FIGHTING MEASURES

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

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.

- Extinguishing Media (suitable) : dry chemical , foam or carbon dioxide Do not use water jet. Water spray should be used to cool containers.
- Fire Fighting Protective Equipment : A self contained breathing apparatus and suitable protective clothing should be worn in fire conditions.

6. ACCIDENTAL RELEASE MEASURES

- Personal Precautions : Eliminate sources of ignition. Ensure suitable personal protection (including respiratory protection) during removal of spillages in a confined area.
- Environmental Precautions : Do not allow to enter drains, sewers or watercourses. If polluted water reaches drainage systems or water courses, immediately inform the appropriate authorities.
- Clean Up Methods : Absorb spillages onto sand, earth or any suitable absorbent material. Do not adsorb onto sawdust or other combustible materials. Transfer to a container

for disposal. Wash the spillage area with water. Transfer spilled vials to a suitable container for disposal. Transfer spilled syringes to a suitable container for disposal. Take care to avoid needles and broken containers.

7. HANDLING AND STORAGE

- Handling : No special precautions are necessary when handling packed product. In case of accident, avoid contact with skin and eyes.
- Storage : Keep only in the original container in a cool, well ventilated place. Keep away from sources of ignition - No Smoking. Protect from light.
- Storage Temperature : 2 - 8 °C
- Storage Life : 3 y

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

- Engineering Controls : Use appropriate controls (e.g. containment, ventilation) as specified in the workplace risk assessment to ensure that the defined occupational exposure limit is not exceeded.

Occupational Exposure Limits

HAZARDOUS

INGREDIENT(S)

TWA

STEL/CEILING(C)

Ethanol	1000 ppm	1,880 mg/m ³	TLV
Fulvestrant		0.001 mg/m ³	COM

It should be noted that this OEL is only relevant for handling the dry material

- Personal Precautions : Selection of personal protective equipment and procedures for use should be based on the workplace risk assessment and local requirements. Respiratory protective equipment and gloves etc. should be changed at appropriate intervals as specified in the workplace risk assessment and in accordance with manufacturers information. Factors that affect breakthrough time are: Concentration of the material and duration of exposure, permeability, contact temperature, etc
- Respirators : NIOSH/MSHA approved respiratory protection device consistent with the work place risk assessment. Consult a

qualified safety and health professional for additional guidance, as needed.

- Protective Clothing : If needed, impervious gloves and apron.
- Eye Protection : Chemical tight goggles.
- Other Protective Equipment : Eyewash station in work area.

9. PHYSICAL AND CHEMICAL PROPERTIES

- Form : vials, pre-filled syringe
- Odor : ethereal

10. STABILITY AND REACTIVITY

- Stability : Sensitive to light.
- Hazardous Reactions : Incompatible materials: oxidizing agents , strong acids .
- Hazardous Decomposition : See 'Fire fighting measures'.
- Product(s)

11. TOXICOLOGICAL INFORMATION

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

- Inhalation : Vapor may be irritant to the upper respiratory 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.
- Skin Contact : May cause skin irritation.
Repeated and/or prolonged contact with the skin may have a degreasing action and cause dermatitis.
May cause skin sensitization in some cases.
Can be absorbed through skin causing systemic toxic effects.
- Eye Contact : The vapor and liquid are irritant. May cause strong stinging and burning sensation. Permanent damage is unlikely.
- Ingestion : Harmful if swallowed.
Consumption of alcohol increases toxic effect.
Ingestion may cause irritation of the gastrointestinal tract.
Adverse effects similar to inhalation may occur.
May cause adverse effects as described under long term.
- Long Term Exposure : Repeated exposure may produce adverse effects on the reproductive systems of men and women., Possible risk of impaired fertility., Possible risk of harm to the unborn child.,

By analogy with Fulvestrant:, Studies in animals have shown that low doses produce embryo/foetotoxic effects in the absence of maternal toxicity., (including embryoletality)., An ingestion study in animals has shown that high doses produce adverse effects on the heart.

12. ECOLOGICAL INFORMATION

Ecotoxicity : No information on this formulation.

13. DISPOSAL CONSIDERATIONS

Chemical Disposal : Disposal should be in accordance with local, state or national legislation.

Disposal Method : Because of a flash point below 140 Deg F, discarded product is a hazardous waste, No. D001, under RCRA, 40 CFR 261.21. Dispose of in facility permitted for hazardous waste.

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

14. TRANSPORT INFORMATION

ICAO/IATA

UN No. : ID 8000

Proper Shipping Name : CONSUMER COMMODITY

Class : 9

Air Pack Instruction

Passenger / Cargo : 910

Air Pack Instruction

Cargo Only : 910

Emergency Response : 9L

Guidance Code

IMO/IMDG

UN No. : 1170

Proper Shipping Name : ETHANOL SOLUTION

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Class : 3
 Marine pollutant : Not classified as a Marine Pollutant
 Packing Group : III
 Packing Instruction : P001
 EMS Number : F-E, S-D

DOT (Department of Transport)

UN No. : -
 Proper Shipping Name : CONSUMER COMMODITY
 Class : ORM-D
 Packing Group : III
 Emergency Response : 171
 Guidebook Code

15. REGULATORY INFORMATION

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. 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 :
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This Material Safety Data Sheet was prepared in accordance with ANSI Standard Z400.1 1993, as modified 1998.

GLOSSARY

COM : In-house occupational exposure limit
 TLV : Threshold Limit Value (ACGIH)
 TLV-C : Threshold Limit Value – Ceiling Limit (ACGIH)
 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 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 Material 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 be used only 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 Material Safety Data Sheet as a source of hazard information.