

SAFETY DATA SHEET



Material Name: Fulvestrant Injection
(Alembic Pharmaceuticals Inc.)

Version: 0.0
Revision date: N.A.

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

1.1 Product Identifier

Material Name Fulvestrant Injection (Alembic Pharmaceuticals Inc.)
Trade Name Not established
Synonyms Fulvestrant PFS for Injection
Chemical Family Mixture – contains an estrogen receptor antagonist
Details of the supplier of the safety data sheet Alembic Pharmaceuticals Inc.
750 Route 202, Bridge water, NJ 08807USA
www.alembicpharmaceuticals.com
Emergency Telephone Alembic (24 hours):18662109797
Contact E-Mail: safety@alembic.co.in

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

Note: This SDS is written to address potential worker health and safety issues associated with the handling of the formulated product/mixture. Workers manufacturing this product/mixture should consult the SDS of each hazardous ingredient for hazard information and handling recommendations.

2. HAZARDS IDENTIFICATION

GHS Classification

Hazard Class	Category	Hazard Statement
Flammable liquids	3	H226
Acute toxicity (Oral)	4	H302
Reproductive toxicity	1B	H360
Effects on or via lactation	NA	H362
Chronic aquatic toxicity	2	H411

GHS label elements



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.

SAFETY DATA SHEET



Material Name: Fulvestrant Injection
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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.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Substance / Mixture Mixture

Hazardous components

Chemical Name	CAS-No.	Concentration (% w/w)	Hazard class	Category	Hazard statements
Fulvestrant	129453-61-8	5	Reproductive toxicant	1B	H360
			Effects on or via lactation	NA	H362
			Chronic aquatic toxicity	1	H410
Ethanol	64-17-5	10	Flammable liquids	2	H225
Benzyl alcohol	100-51-6	10	Acute toxicity	4	H302
			Acute toxicity	4	H332
Benzyl benzoate	120-51-4	15	Acute toxicity	4	H302
			Chronic Aquatic toxicity	2	H411

4. FIRST AID MEASURES

Description of 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	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.

SAFETY DATA SHEET



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5. FIRE FIGHTING 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.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	Ensure suitable personal protection during removal of spillages. Eliminate sources of ignition
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.

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

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Ethanol	64-17-5	TWA	1,000 ppm 1,880 mg/m ³	AU OEL
		STEL	1,000 ppm	ACGIH
Fulvestrant	129453-61-8	TWA	0.001 mg/m ³	COM; HYG

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

SAFETY DATA SHEET



Material Name: Fulvestrant Injection
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Revision date: N.A.

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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	Liquid
Colour	Clear, colorless to yellow color viscous solution
Odour	Ethereal
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	29°C
Evaporation rate	No data available
Upper explosion limit	3.5 %(V)
Lower explosion limit	19 %(V)
Vapour pressure	No data available
Relative vapour density	No data available
Relative density	No data available
Solubility	
Water solubility	No data available
Solubility in other solvents	No data available
Partition coefficient: n-octanol/water	No data available
Auto-ignition temperature	365 °C
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

SAFETY DATA SHEET



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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 vapour 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 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. 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	Rare cases of skin sensitization have been reported
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

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

SAFETY DATA SHEET



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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

Component: 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.

Bio accumulative potential

Component: 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

Component: Fulvestrant

Mobility: The substance is essentially insoluble in water.

Distribution among environmental compartments: No information available.

Other adverse effects

No data available

13. DISPOSAL CONSIDERATIONS

Disposal method for 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.

Disposal method for Contaminated packaging Empty container will retain residue. Observe all hazard precautions.

14. TRANSPORT INFORMATION

ICAO/IATA

UN No.

1993

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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)
Class	3
Packing Group	III
Marine pollutant	Marine pollutant
ADR	
Proper Shipping Name	Flammable liquid, n.o.s. (ETHANOL, FULVESTRANT)
Class	3
Packing Group	III
Environmental hazards	Environmentally hazardous

15. REGULATORY INFORMATION

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
Fulvestrant	129453-61-8
AICS	Not listed
ENCS	Not listed
ISHL	Not listed
IECSC	Not listed
TCSI	Not listed
TSCA	Not On TSCA Inventory

16. OTHER INFORMATION

Hazard statements	H225 : Highly flammable liquid and vapour. H226 : Flammable liquid and vapour. H302 : Harmful if swallowed. H332 : Harmful if inhaled. H360 : May damage the unborn child. Suspected of damaging fertility. H362 : May cause harm to breast-fed children. H410 : Very toxic to aquatic life with long lasting effects. H411 : Toxic to aquatic life with long lasting effects.
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Full text of abbreviations	AICS - Australian Inventory of Chemical Substances; ANTT - National Agency for Transport by Land of Brazil; COM – In-house occupational exposure limit; DSL - Domestic Substances List (Canada); ENCS - Existing and New Chemical Substances (Japan); GHS - Globally Harmonized System; HYG – Analytical method for occupational exposure monitoring; IATA - International Air Transport Association; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization;
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IECSC - Inventory of Existing Chemical Substances in China;
IMDG - International Maritime Dangerous Goods;
IMO - International Maritime Organization;
ISHL - Industrial Safety and Health Law (Japan);
n.o.s. - Not Otherwise Specified;
NOM - Official Mexican Norm;
OECD - Organization for Economic Co-operation and Development;
REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals;
SDS - Safety Data Sheet;
TSCA - Toxic Substances Control Act (United States);
TWA – Long-term exposure limit 8h time-weighted average;
UN - United Nations;

Data Sources

1. SDS of Faslodex solution for Injection, AstraZeneca Pty Ltd.
https://www.medline.com/media/catalog/Docs/MSDS/MSD_SDSD14403.pdf

Prepared By

Alembic Pharmaceuticals Ltd, Vadodara, Gujarat, India – 390003

Date of Issue

14/09/2020

Revision date

N.A.

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its issue. The information given is designed only as 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.

End of Safety Data Sheet