

SAFETY DATA SHEET

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Revision Number 00

1. IDENTIFICATION

Product Name Fulvestrant Injection, USP 50 mg/mL (5 mL)

Type of Container Vials (50 mg/mL (5 mL))

Synonyms C32H47F5O3S

Recommended Use Specified quality tests and assay use only.

Manufacturer Name And Address

Amneal Pharmaceuticals Pvt. Ltd.
Plot No.15,PHARMEZ-SEZ, Sarkhej-Bavla Highway,
Ta. Sanad , Dist. Ahmedabad-382220, Gujarat, India.

Emergency Telephone number

+91-2714-671600

2. HAZARDS IDENTIFICATION

Carcinogen List

Substance	IARC	NTP	OSHA
Fulvestrant	Not Listed	Not Listed	Not Listed

Emergency Overview Potential Acute Health Effects: Slightly hazardous in case of skin contact (irritant), of eye contact (irritant), of ingestion, of inhalation.

Hazard Class Not applicable

Signal word Not applicable

Symbol Not applicable

Precautionary Statement P-260- Do not breathe vapor/dust/gas/mist/fumes/spray

Hazard Statement Not applicable

Product Name: Fulvestrant Injection, USP

Occupational Exposure Potential Information on the absorption of this product via inhalation or skin contact is not available. Avoid liquid aerosol generation and skin contact.

Signs and Symptoms None known from occupational exposures. Adverse effects have included gastrointestinal distress and fever from parenteral administration.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name Fulvestrant

Chemical Formula C₃₂H₄₇F₅O₃S

Preparation Non-hazardous ingredients include Water for Injection. Hazardous ingredients present at less than 1% include sodium chloride; sodium hydroxide and/or hydrochloric acid are added to adjust the pH.

Component	Approximate Percent by Weight (% W/V)	CAS Number	RTECS Number
Fulvestrant	5 %	129453-61-8	NA
Benzyl Alcohol	10 %	100-51-6	NA
Benzyl Benzoate USP	15 %	120-51-4	NA

4. FIRST-AID MEASURES

Eye contact Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Skin contact In case of contact, immediately flush skin with plenty of water. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Inhalation If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention if symptoms appear.

Ingestion Gastrointestinal effects (may include nausea, upset stomach, loss of appetite). Cardiovascular effects (may include fluctuations in heart rate, changes in blood pressure, chest pain). Nervous system effects (may include drowsiness, confusion, hallucinations, convulsions, visual disturbances, headache, coma). May irritate digestive tract. Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. If large quantities of this material are swallowed, call a physician immediately.

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5. FIRE-FIGHTING MEASURES

Flammability	Not determined
Flash point:	Not determined
Auto ignition Temperature	Not available
Fire & Explosion Hazard	Not available.
Extinguishing media	Use foam or all-purpose dry chemicals to extinguish.
Special Fire Fighting Procedures	No special provisions required beyond normal fire fighting equipment such as flame and chemical resistant clothing and self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions: Keep unnecessary personnel away. Use suitable protective equipment (Section 8). Follow all firefighting procedures (Section 5).

Spill Cleanup and Disposal Isolate area around spill. Put on suitable protective clothing and equipment as specified by site spill procedures. Absorb the liquid with suitable material and clean affected area with soap and water. Dispose of spill materials according to the applicable federal, state, or local regulations.

7. HANDLING AND STORAGE

Handling No special handling required under conditions of normal product use.

Storage No special storage required for hazard control. For product protection, follow storage recommendations noted on the product case label, the primary Container label, or the product insert.

Special Precautions No special precautions required for hazard control.

Storage Conditions Store your new, unused fulvestrant Injection in the original carton in a refrigerator at 36° to 46°F (2° to 8°C). Protect fulvestrant injection from light, store in carton until time of use. Follow instructions provided in packaging.

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8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Occupational Exposure Limits

Component	OSHA-Time Weighted Average:	OSHA-Short Term Exposur	OSHA-Ceiling Limits	ACGIH-Time Weighted Average:	ACGIH-Short Term Exposur	ACGIH-Ceiling Limit Value:
Fulvestrant 129453-61-8	None	None	None	None	None	None
Benzyl Alcohol 100-51-6	None	None	None	None	None	None
Benzyl Benzoate USP 120-51-4	None	None	None	None	None	None
Water 7732-18-5	None	None	None	None	None	None

Components with workplace control parameters

Component	CAS No.	Value	Control parameters	Basis
Fulvestrant	129453-61-8	N/A	N/A	N/A

Engineering measures: No special containment is required. Provide general or local exhaust ventilation.

Personal protective equipment:

Respiratory protection: Perform exposure monitoring for this product and its components to ensure that employees are not exposed to levels greater than applicable regulatory limits. If exposure levels exceed regulatory limits, implement a respiratory protection program including respiratory protection that is in compliance with OSHA 29 CFR1910.134 (in the US) or equivalent regulation in other regions. Fire fighting requires the use of a self-contained breathing apparatus with full face piece and positive pressure mode.

Hand protection: Use chemical resistant, impervious gloves.

Skin and body protection: Work uniform or laboratory coat.

Eye protection: Safety glasses with side-shields. Goggles, face shield, or other full-face protection if potential exists for direct exposure to aerosols or splashes.

Engineering Controls Engineering controls are normally not needed during the normal use of this product. Handle product in a well-ventilated area.

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9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance/Physical State	Liquid
Color	Colorless aqueous solution.
Odor	NA
Odor Threshold:	NA
pH:	7.0-7.5
Melting point/Freezing point:	NA
Initial Boiling Point/Boiling Point	NA
Range:	
Evaporation Rate:	NA
Flammability (solid, gas):	NA
Upper/Lower Flammability or Explosive Limits:	NA
Vapor Pressure:	NA
Vapor Density:	NA
Specific Gravity:	NA
Solubility:	Soluble in water
Partition coefficient: n-octanol/water:	NA
Auto-ignition temperature:	NA
Decomposition temperature:	NA

10. STABILITY AND REACTIVITY

Stability	Stable under recommended storage conditions.
Reactivity	Not determined.
Chemical Stability	Stable under standard use and storage conditions.
Hazardous Reactions	Not determined.
Conditions to avoid	Oxidizing agent.
Incompatibilities	Not determined.
Hazardous Polymerization	Not applicable.
Hazardous decomposition products	Not determined.

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11. TOXICOLOGICAL INFORMATION

Acute Toxicity

Not determined for the product formulation. Information for the ingredients is as follows:

Ingredient(s)	Percent	Test Type	Route of Administration	Value	Units	Species
Fulvestrant	100	LD50	Oral	NA	mg/kg mg/kg mg/kg	Rat Mouse Rabbit
Fulvestrant	100	LD50	Intravenous	NA	mg/kg mg/kg	Mouse Rabbit

Acute Toxicity:

Signs and symptoms of overexposure to Anticholinergic drugs may include lethargy, drowsiness, coma, confusion, agitation, hallucinations, convulsions, visual disturbances, dry flushed skin, dry mouth, decreased bowel sounds, urinary retention, increased heart rate, high blood pressure, and supraventricular arrhythmias.

Chronic Toxicity:

Contains material which may cause damage to the following organs: skin, eye, lens or Cornea.

Carcinogenic effects:

Not classified or listed by IARC, NTP, OSHA, EU and ACGIH. No data is available on the product itself.

Mutagenic effects:

No data is available on the product itself.

Reproductive toxicity:

May impair fertility based on animal data. Not considered fetotoxic based on animal data. See patient package insert for additional information.

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12. ECOLOGICAL INFORMATION

Environmental properties:

Component	Eco toxicity - Water Flea Data	Fish Species Eco toxicity	Eco toxicity - Freshwater Algae Data	Microtox Etoxicity Data
Fulvestrant 129453-61-8	None.	None.	None.	None.
Benzyl Alcohol 100-51-6	= 23 mg/L EC50 water flea	LC50 (96 hr) fathead minnow:460 mg/L: Static, 18-22°C; LC50 (96 hr) bluegill:10 mg/L: Static.	None.	= 63.7 mg/L EC50 Photobacterium phosphoreum = 71.4 mg/L EC50 Photobacterium phosphoreum

Ecotoxicity effects: No data available

Bioaccumulation: No data available

Mobility in Soil Not determined for product.

13. DISPOSAL CONSIDERATIONS

Waste Disposal All waste materials must be properly characterized. Further, disposal should be performed in accordance with the federal, state or local regulatory requirements.

Container Handling and Disposal Dispose of container and unused contents in accordance with federal, state and local regulations.

14. TRANSPORT INFORMATION

ADR/ADG/ DOT STATUS: Not regulated

IMDG STATUS: Not regulated

ICAO/IATA STATUS: Not regulated

Transport Comments: None

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15. REGULATORY INFORMATION

USA Regulations

Substance	Weight %	TSCA Status	CERCLA Status	SARA 302 Status	SARA 313 Status	PROP 65 Status
Fulvestrant	5.0	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Benzyl alcohol	10.0	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Benzyl Benzoate	15.0	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed

RCRA Status Not Listed

U.S. OSHA Classification TSCA Inventory List: The product is exempt from TSCA, it is FDA Regulated
Possible Irritant

Hazard Class Not Applicable

Hazard Category Not Applicable

Signal Word Not Applicable

Symbol Not Applicable

Prevention P260 - Do not breathe dust/fume/gas/mist/vapors/spray.

Hazard Statement Not applicable

Response IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical attention. Wash hands after handling.

Get medical attention if you feel unwell

EU Classification*

*Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive. Information provided below is for the pure drug substance Fulvestrant.

Classification(s): Not Applicable

Symbol: Not Applicable

Indication of Danger: Not Applicable

Risk Phrases: Not Applicable

Safety Phrases:
S23 - Do not breathe vapor.
S24/25 - Avoid contact with skin and eyes.
S37/39 - Wear suitable gloves and eye/face protection.

WHMIS (Canada): Not controlled under WHMIS (Canada).

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16. OTHER INFORMATION:

Notes:

ACGIH TLV	American Conference of Governmental Industrial Hygienists – Threshold Limit Value
CAS	Chemical Abstracts Service Number
CERCLA	US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act
DOT	US Department of Transportation Regulations
EEL	Employee Exposure Limit
IATA	International Air Transport Association
LD50	Dosage producing 50% mortality
NA	Not applicable/Not available
NE	Not established
NIOSH	National Institute for Occupational Safety and Health
OSHA PEL	US Occupational Safety and Health Administration – Permissible Exposure Limit
Prop 65	California Proposition 65
RCRA	US EPA, Resource Conservation and Recovery Act
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
STEL	15-minute Short Term Exposure Limit
TSCA	Toxic Substance Control Act
TWA	8-hour Time Weighted Average

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Further information	Not available.

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