

Fulvestrant Injection

Safety Data Sheet

SECTION 1: Identification

1.1. Identification

Product name : Fulvestrant Injection
Other means of identification : 250 mg per 5 mL (50 mg/mL) Single Dose Pre-filled syringes packaged in a carton of 2, NDC 55150-394-02

1.2. Relevant identified uses of the substance or mixture and uses advised against

Use of the substance/mixture : Pharmaceutical

1.3. Details of the supplier of the safety data sheet

Eugia US LLC
279 Princeton Hightstown Road
East Windsor, NJ 08520

1.4. Emergency telephone number

Emergency number : 1-888-238-7880

SECTION 2: Hazard(s) identification

2.1. Classification of the substance or mixture

GHS US classification

Not classified

2.2. Label elements

GHS US labeling

No labeling applicable

2.3. Other hazards

No additional information available

2.4. Unknown acute toxicity (GHS US)

Not applicable

SECTION 3: Composition/Information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%	GHS US classification
Castor oil	(CAS-No.) 8001-79-4	60	Not classified
Benzyl benzoate	(CAS-No.) 120-51-4	15	Acute Tox. 4 (Oral), H302
Ethyl alcohol	(CAS-No.) 64-17-5	10	Flam. Liq. 2, H225 Carc. 1A, H350
Benzyl alcohol	(CAS-No.) 100-51-6	10	Acute Tox. 4 (Oral), H302 Acute Tox. 4 (Inhalation), H332
Fulvestrant	(CAS-No.) 129453-61-8	5	Not classified

Full text of hazard classes and H-statements : see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures after inhalation : If not breathing, give artificial respiration.
First-aid measures after skin contact : Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.
First-aid measures after eye contact : In case of dust contact with eyes, rinse immediately with plenty of water.
First-aid measures after ingestion : Go into open air and ventilate suspected area.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/effects after inhalation : May cause respiratory irritation.
Symptoms/effects after skin contact : May cause skin irritation.
Symptoms/effects after eye contact : May cause eye irritation.

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Symptoms/effects after ingestion : May be harmful if swallowed.

4.3. Indication of any immediate medical attention and special treatment needed

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Use extinguishing media appropriate for surrounding fire.

Unsuitable extinguishing media : None.

5.2. Special hazards arising from the substance or mixture

Fire hazard : None known.

5.3. Advice for firefighters

Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : No special measures required.

6.1.1. For non-emergency personnel

No additional information available

6.1.2. For emergency responders

6.2. Environmental precautions

Prevent entry to sewers and public waters.

6.3. Methods and material for containment and cleaning up

For containment : Stop the flow of material, if this is without risk.

Methods for cleaning up : Recycle product or dispose safely.

6.4. Reference to other sections

No additional information available

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Do not eat, drink or smoke when using this product.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : REFRIGERATE, 2° to 8°C (36° to 46°F).

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Ethyl alcohol (64-17-5)		
ACGIH	ACGIH OEL STEL [ppm]	1000 ppm
OSHA	OSHA PEL (TWA) [1]	1900 mg/m ³
OSHA	OSHA PEL (TWA) [2]	1000 ppm
IDLH	IDLH [ppm]	3300 ppm (10% LEL)
NIOSH	NIOSH REL (TWA)	1900 mg/m ³
NIOSH	NIOSH REL TWA [ppm]	1000 ppm
Benzyl alcohol (100-51-6)		
AIHA	WEEL TWA [ppm]	10 ppm
Benzyl benzoate (120-51-4)		
Not applicable		
Castor oil (8001-79-4)		
Not applicable		

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Not applicable

8.2. Exposure controls

Appropriate engineering controls	: Local exhaust and general ventilation must be adequate to meet exposure standards.
Hand protection	: Use neoprene or rubber gloves.
Eye protection	: Wear protective goggles.
Skin and body protection	: Wear suitable working clothes.
Respiratory protection	: Wear NIOSH approved respirator when handling.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Appearance	: Clear.
Color	: Colorless to yellow
Odor	: Odorless
Odor threshold	: No data available
pH	: No data available
Melting point	: No data available
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Relative evaporation rate (butyl acetate=1)	: No data available
Flammability	: No data available
Vapor pressure	: No data available
Relative vapor density at 20°C	: No data available
Relative density	: No data available
Solubility	: No data available
Partition coefficient n-octanol/water (Log Pow)	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosion limits	: No data available
Explosive properties	: No data available
Oxidizing properties	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available

10.2. Chemical stability

The product is stable at normal handling and storage conditions.

10.3. Possibility of hazardous reactions

Will not occur.

10.4. Conditions to avoid

Air contact.

10.5. Incompatible materials

None known.

10.6. Hazardous decomposition products

None known.

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SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified

Ethyl alcohol (64-17-5)	
LD50 oral rat	7060 mg/kg
LC50 Inhalation - Rat	124.7 mg/l/4h
ATE US (oral)	7060 mg/kg

Benzyl alcohol (100-51-6)	
LD50 oral rat	1230 mg/kg
LD50 dermal rabbit	2 g/kg
LC50 Inhalation - Rat	8.8 mg/l/4h
ATE US (oral)	1230 mg/kg body weight
ATE US (dermal)	2000 mg/kg body weight
ATE US (gases)	4500 ppmV/4h
ATE US (vapors)	8.8 mg/l/4h
ATE US (dust, mist)	1.5 mg/l/4h

Benzyl benzoate (120-51-4)	
LD50 oral rat	500 mg/kg
LD50 dermal rabbit	4000 mg/kg
ATE US (oral)	500 mg/kg body weight
ATE US (dermal)	4000 mg/kg body weight

Skin corrosion/irritation : Not classified
Serious eye damage/irritation : Not classified
Respiratory or skin sensitization : Not classified
Germ cell mutagenicity : Not classified
Carcinogenicity : Not classified

Ethyl alcohol (64-17-5)	
IARC group	1 - Carcinogenic to humans
In OSHA Hazard Communication Carcinogen list	Yes

Reproductive toxicity : Not classified
STOT-single exposure : Not classified

STOT-repeated exposure : Not classified

Aspiration hazard : Not classified

SECTION 12: Ecological information

12.1. Toxicity

Ethyl alcohol (64-17-5)	
LC50 - Fish [1]	12 – 16 ml/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])
EC50 - Crustacea [1]	9268 – 14221 mg/l (Exposure time: 48 h - Species: Daphnia magna)
LC50 - Fish [2]	> 100 mg/l (Exposure time: 96 h - Species: Pimephales promelas [static])
EC50 - Crustacea [2]	2 mg/l (Exposure time: 48 h - Species: Daphnia magna [Static])

Benzyl alcohol (100-51-6)	
LC50 - Fish [1]	460 mg/l (Exposure time: 96 h - Species: Pimephales promelas [static])
EC50 - Crustacea [1]	23 mg/l (Exposure time: 48 h - Species: water flea)
LC50 - Fish [2]	10 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static])

12.2. Persistence and degradability

No additional information available

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12.3. Bioaccumulative potential

Ethyl alcohol (64-17-5)	
Partition coefficient n-octanol/water (Log Pow)	-0.32
Benzyl alcohol (100-51-6)	
Partition coefficient n-octanol/water (Log Pow)	1.1
Benzyl benzoate (120-51-4)	
Partition coefficient n-octanol/water (Log Pow)	4

12.4. Mobility in soil

No additional information available

12.5. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Product/Packaging disposal recommendations : Dispose of contents/container in accordance with local/regional/national/international regulations.

SECTION 14: Transport information

Department of Transportation (DOT)

In accordance with DOT

Not applicable

International Air Transport Association (IATA)

In accordance with IATA

Not applicable

SECTION 15: Regulatory information

15.1. US Federal regulations

Ethyl alcohol (64-17-5)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
Benzyl alcohol (100-51-6)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
Benzyl benzoate (120-51-4)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
Castor oil (8001-79-4)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	

15.2. US State regulations

Ethyl alcohol (64-17-5)				
U.S. - California - Proposition 65 - Carcinogens List	U.S. - California - Proposition 65 - Developmental Toxicity	U.S. - California - Proposition 65 - Reproductive Toxicity - Female	U.S. - California - Proposition 65 - Reproductive Toxicity - Male	No significant risk level (NSRL)
Yes	Yes	No	No	

Ethyl alcohol (64-17-5)	
U.S. - Massachusetts - Right To Know List	
U.S. - Minnesota - Hazardous Substance List	
U.S. - New Jersey - Right to Know Hazardous Substance List	
U.S. - Pennsylvania - RTK (Right to Know) List	

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Benzyl alcohol (100-51-6)

U.S. - Massachusetts - Right To Know List
U.S. - Minnesota - Hazardous Substance List
U.S. - Pennsylvania - RTK (Right to Know) List

SECTION 16: Other information

Full text of H-phrases:

Acute Tox. 4 (Inhalation)	Acute toxicity (inhalation) Category 4
Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
Carc. 1A	Carcinogenicity Category 1A
Flam. Liq. 2	Flammable liquids Category 2
H225	Highly flammable liquid and vapor
H302	Harmful if swallowed
H332	Harmful if inhaled
H350	May cause cancer

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.