

SDS Title: Fulvestrant Injection Safety Data Sheet	SDS Number: SDS-000019	Page Number: Page 1 of 20
Function: Regulatory Affairs	Effective Date: July 9, 2025	Version number: 4.0

Section 1. Identification

GHS product identifier : Fulvestrant Injection
Other means of identification : Fulvestrant Injection
Product type : Liquid.

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

Product use : Pharmaceuticals (For intended use only.)
 Observe technical data sheet/instructions for use.
 Specific Treatments: Antineoplastic agents. (breast tumors/Cancer)

Area of application : Professional applications.

Supplier's details : Meitheal Pharmaceuticals, Inc.
 8700 W. Bryn Mawr, Suite 600S
 Chicago, IL 60631

Telephone: 224-443-4617
 www.meithealpharma.com

e-mail address of person responsible for this SDS : info@meithealpharma.com

Emergency telephone number (with hours of operation) : 844-824-8426 (Monday - Friday, 08:00 - 18:00 CST)

Section 2. Hazards identification

OSHA/HCS status : This material is considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200).

Classification of the substance or mixture : H226 FLAMMABLE LIQUIDS - Category 3
 H315 SKIN IRRITATION - Category 2
 H319 EYE IRRITATION - Category 2A
 H317 SKIN SENSITIZATION - Category 1
 H360 TOXIC TO REPRODUCTION - Category 1B
 H362 TOXIC TO REPRODUCTION - Effects on or via lactation
 H373 SPECIFIC TARGET ORGAN TOXICITY (REPEATED EXPOSURE) - Category 2

GHS label elements

Hazard pictograms :





SDS Title: Fulvestrant Injection Safety Data Sheet	SDS Number: SDS-000019	Page Number: Page 2 of 20
Function: Regulatory Affairs	Effective Date: July 9, 2025	Version number: 4.0

Section 2. Hazards identification

Signal word	: Danger
Hazard statements	: H226 - Flammable liquid and vapor. H315 - Causes skin irritation. H317 - May cause an allergic skin reaction. H319 - Causes serious eye irritation. H360 - May damage fertility or the unborn child. H362 - May cause harm to breast-fed children. H373 - May cause damage to organs through prolonged or repeated exposure. (liver)
Precautionary statements	
Prevention	: P201 - Obtain special instructions before use. P202 - Do not handle until all safety precautions have been read and understood. P280 - Wear protective gloves, protective clothing and eye or face protection. P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P260 - Do not breathe vapor. P263 - Avoid contact during pregnancy and while nursing. P270 - Do not eat, drink or smoke when using this product. P264 - Wash thoroughly after handling. P272 - Contaminated work clothing must not be allowed out of the workplace.
Response	: P308 + P313 - IF exposed or concerned: Get medical advice or attention. P303 + P361 + P353 - IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water. P333 + P313 - If skin irritation or rash occurs: Get medical advice or attention. P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337 + P313 - If eye irritation persists: Get medical advice or attention.
Storage	: P405 - Store locked up.
Disposal	: P501 - Dispose of contents and container in accordance with all local, regional, national and international regulations.
Hazards not otherwise classified	: None known.
Hazards identified when used	: No known significant effects or critical hazards.

Section 3. Composition/information on ingredients

Substance/mixture	: Mixture
Other means of identification	: Fulvestrant Injection

SDS Title: Fulvestrant Injection Safety Data Sheet	SDS Number: SDS-000019	Page Number: Page 3 of 20
Function: Regulatory Affairs	Effective Date: July 9, 2025	Version number: 4.0

Section 3. Composition/information on ingredients

Ingredient name	Synonyms	%	Identifiers
Castor oil	-	≥60 - ≤80	CAS: 8001-79-4
benzyl benzoate	-	≥10 - ≤30	CAS: 120-51-4
Ethanol	Ethyl alcohol	≥7 - ≤13	CAS: 64-17-5
benzyl alcohol	Benzyl alcohol	≥7 - ≤13	CAS: 100-51-6
fulvestrant	-	≥3 - ≤7	CAS: 129453-61-8
nitrogen	Nitrogen	≥0.1 - ≤1	CAS: 7727-37-9

Any concentration shown as a range is to protect confidentiality or is due to batch variation.

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified and hence require reporting in this section.

Section 4. First aid measures

Description of necessary first aid measures

- Eye contact** : Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse for at least 10 minutes. Get medical attention.
- Inhalation** : Remove victim to fresh air and keep at rest in a position comfortable for breathing. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Get medical attention. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband. In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.
- Skin contact** : Wash with plenty of soap and water. Remove contaminated clothing and shoes. Wash contaminated clothing thoroughly with water before removing it, or wear gloves. Continue to rinse for at least 10 minutes. Get medical attention. In the event of any complaints or symptoms, avoid further exposure. Wash clothing before reuse. Clean shoes thoroughly before reuse.
- Ingestion** : Wash out mouth with water. Remove dentures if any. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Stop if the exposed person feels sick as vomiting may be dangerous. Do not induce vomiting unless directed to do so by medical personnel. If vomiting occurs, the head should be kept low so that vomit does not enter the lungs. Get medical attention. Never give anything by mouth to an unconscious person. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.

Most important symptoms/effects, acute and delayed

Potential acute health effects

- Eye contact** : Causes serious eye irritation.
- Inhalation** : No known significant effects or critical hazards.
- Skin contact** : Causes skin irritation. May cause an allergic skin reaction.

SDS Title: Fulvestrant Injection Safety Data Sheet	SDS Number: SDS-000019	Page Number: Page 4 of 20
Function: Regulatory Affairs	Effective Date: July 9, 2025	Version number: 4.0

Section 4. First aid measures

Ingestion : No known significant effects or critical hazards.

Over-exposure signs/symptoms

Eye contact : Adverse symptoms may include the following:
pain or irritation
watering
redness

Inhalation : Adverse symptoms may include the following:
reduced fetal weight
increase in fetal deaths
skeletal malformations

Skin contact : Adverse symptoms may include the following:
irritation
redness
reduced fetal weight
increase in fetal deaths
skeletal malformations

Ingestion : Adverse symptoms may include the following:
reduced fetal weight
increase in fetal deaths
skeletal malformations

Indication of immediate medical attention and special treatment needed, if necessary

Notes to physician : In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.

Specific treatments : No specific treatment.

Protection of first-aiders : No action shall be taken involving any personal risk or without suitable training. If it is suspected that fumes are still present, the rescuer should wear an appropriate mask or self-contained breathing apparatus. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Wash contaminated clothing thoroughly with water before removing it, or wear gloves.

See toxicological information (Section 11)

Section 5. Fire-fighting measures

Extinguishing media

Suitable extinguishing media : Use dry chemical, CO₂, water spray (fog) or foam.

Unsuitable extinguishing media : Do not use water jet.

Specific hazards arising from the chemical : Flammable liquid and vapor. Runoff to sewer may create fire or explosion hazard. In a fire or if heated, a pressure increase will occur and the container may burst, with the risk of a subsequent explosion.

SDS Title: Fulvestrant Injection Safety Data Sheet	SDS Number: SDS-000019	Page Number: Page 5 of 20
Function: Regulatory Affairs	Effective Date: July 9, 2025	Version number: 4.0

Section 5. Fire-fighting measures

- Hazardous thermal decomposition products** : Decomposition products may include the following materials:
carbon dioxide
carbon monoxide
sulfur oxides
halogenated compounds
carbonyl halides
- Special protective actions for fire-fighters** : Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training. Move containers from fire area if this can be done without risk. Use water spray to keep fire-exposed containers cool.
- Special protective equipment for fire-fighters** : Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

Section 6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

- For non-emergency personnel** : No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilled material. Shut off all ignition sources. No flares, smoking or flames in hazard area. Avoid breathing vapor or mist. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment.
- For emergency responders** : If specialized clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".
- Environmental precautions** : Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

Methods and materials for containment and cleaning up

- Small spill** : Stop leak if without risk. Move containers from spill area. Use spark-proof tools and explosion-proof equipment. Absorb with an inert material and place in an appropriate waste disposal container. Dispose of via a licensed waste disposal contractor.
- Large spill** : Stop leak if without risk. Move containers from spill area. Use spark-proof tools and explosion-proof equipment. Approach release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. Dispose of via a licensed waste disposal contractor. Contaminated absorbent material may pose the same hazard as the spilled product. Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations.

SDS Title: Fulvestrant Injection Safety Data Sheet	SDS Number: SDS-000019	Page Number: Page 6 of 20
Function: Regulatory Affairs	Effective Date: July 9, 2025	Version number: 4.0

Section 7. Handling and storage

Precautions for safe handling

- Protective measures** : Put on appropriate personal protective equipment (see Section 8). Persons with a history of skin sensitization problems should not be employed in any process in which this product is used. Avoid exposure - obtain special instructions before use. Avoid contact during pregnancy or while nursing. Do not handle until all safety precautions have been read and understood. Do not get in eyes or on skin or clothing. Do not breathe vapor or mist. Do not ingest. Use only with adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Do not enter storage areas and confined spaces unless adequately ventilated. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Store and use away from heat, sparks, open flame or any other ignition source. Use explosion-proof electrical (ventilating, lighting and material handling) equipment. Use only non-sparking tools. Take precautionary measures against electrostatic discharges. Empty containers retain product residue and can be hazardous. Do not reuse container.

- Advice on general occupational hygiene** : Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures.

- Conditions for safe storage, including any incompatibilities** : Store in accordance with local regulations. Store in a segregated and approved area. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Store locked up. Eliminate all ignition sources. Separate from oxidizing materials. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination. See Section 10 for incompatible materials before handling or use.

Section 8. Exposure controls/personal protection

Control parameters

Occupational exposure limits

Ingredient name	Exposure limits
Castor oil benzyl benzoate Ethanol	None. None. ACGIH TLV (United States, 1/2024) A3. STEL 15 minutes: 1000 ppm. NIOSH REL (United States, 10/2020) TWA 10 hours: 1000 ppm. TWA 10 hours: 1900 mg/m ³ . OSHA PEL (United States, 5/2018) TWA 8 hours: 1000 ppm. TWA 8 hours: 1900 mg/m ³ . CAL OSHA PEL (United States, 1/2025) TWA 8 hours: 1900 mg/m ³ . TWA 8 hours: 1000 ppm.

SDS Title: Fulvestrant Injection Safety Data Sheet	SDS Number: SDS-000019	Page Number: Page 7 of 20
Function: Regulatory Affairs	Effective Date: July 9, 2025	Version number: 4.0

Section 8. Exposure controls/personal protection

benzyl alcohol fulvestrant nitrogen	OARS WEEL (United States, 9/2024) TWA 8 hours: 10 ppm. None. ACGIH TLV (United States, 1/2024) Oxygen depletion [asphyxiant].
---	--

Biological exposure indices

None known.

Appropriate engineering controls

: Use only with adequate ventilation. Use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure to airborne contaminants below any recommended or statutory limits. The engineering controls also need to keep gas, vapor or dust concentrations below any lower explosive limits. Use explosion-proof ventilation equipment.

Environmental exposure controls

: Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.

Individual protection measures

Hygiene measures

: Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

Eye/face protection

: Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: chemical splash goggles.

Skin protection

Hand protection

: Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. Considering the parameters specified by the glove manufacturer, check during use that the gloves are still retaining their protective properties. It should be noted that the time to breakthrough for any glove material may be different for different glove manufacturers. In the case of mixtures, consisting of several substances, the protection time of the gloves cannot be accurately estimated.

Body protection

: Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product. When there is a risk of ignition from static electricity, wear anti-static protective clothing. For the greatest protection from static discharges, clothing should include anti-static overalls, boots and gloves.

SDS Title: Fulvestrant Injection Safety Data Sheet	SDS Number: SDS-000019	Page Number: Page 8 of 20
Function: Regulatory Affairs	Effective Date: July 9, 2025	Version number: 4.0

Section 8. Exposure controls/personal protection

- Other skin protection** : Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
- Respiratory protection** : Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use.

Section 9. Physical and chemical properties

The conditions of measurement of all properties are at standard temperature and pressure unless otherwise indicated.

Appearance

- Physical state** : Liquid. [Viscous]
- Color** : Colorless./Yellow.
- Odor** : Odorless.
- Odor threshold** : Not available.
- pH** : Not applicable.
- Melting point** : Not applicable.
- Boiling point or initial boiling point and boiling range** : Not applicable.
- Flash point** : Closed cup: 37.8 to 61°C (100 to 141.8°F)
Open cup: Not applicable.
- Evaporation rate** : Not applicable.
- Flammability** : Not available.
- Lower and upper explosion limit/flammability limit** : Not applicable.
- Vapor pressure** : Not applicable.
- Relative vapor density** : Not available.
- Relative density** : 0.983 [Water = 1]
- Density** : 0.983 g/cm³ [25°C (77°F)]
- Solubility(ies)** : Not available.
- Partition coefficient: n-octanol/water** : Not applicable.
- Auto-ignition temperature** : Not applicable.
- Decomposition temperature** : Not applicable.
- SADT** : Not available.
- Viscosity** : Dynamic (room temperature): 65 to 85 mPa·s (65 to 85 cP)
Kinematic (room temperature): Not applicable.
Kinematic (40°C (104°F)): Not applicable.
- Particle characteristics**
- Median particle size** : Not applicable.

SDS Title: Fulvestrant Injection Safety Data Sheet	SDS Number: SDS-000019	Page Number: Page 9 of 20
Function: Regulatory Affairs	Effective Date: July 9, 2025	Version number: 4.0

Section 9. Physical and chemical properties

Other information
Physical/chemical properties comments : No additional information.

Section 10. Stability and reactivity

- Reactivity** : No specific test data related to reactivity available for this product or its ingredients.
- Chemical stability** : The product is stable.
- Possibility of hazardous reactions** : Under normal conditions of storage and use, hazardous reactions will not occur.
Under normal conditions of storage and use, hazardous polymerization will not occur.
- Conditions to avoid** : Avoid all possible sources of ignition (spark or flame). Do not pressurize, cut, weld, braze, solder, drill, grind or expose containers to heat or sources of ignition.
- Incompatible materials** : Reactive or incompatible with the following materials:
oxidizing materials
- Hazardous decomposition products** : Under normal conditions of storage and use, hazardous decomposition products should not be produced.

Section 11. Toxicological information

Information on toxicological effects

Acute toxicity

Product/ingredient name	Result	
Castor oil	Rat - Oral - LD50 10 g/kg	
benzyl benzoate	Rabbit - Dermal - LD50 4 g/kg	
	Rat - Oral - LD50 1700 mg/kg	
Ethanol	Rat - Oral - LD50 7 g/kg	
	Rat - Inhalation - LC50 Vapor 124700 mg/m ³ [4 hours]	
benzyl alcohol	Rat - Oral - LD50 1230 mg/kg	<u>Toxic effects:</u> Behavioral - Somnolence (general depressed activity) Behavioral - Excitement Behavioral - Coma
	Rabbit - Dermal - LD50 2000 mg/kg	



SDS Title: Fulvestrant Injection Safety Data Sheet	SDS Number: SDS-000019	Page Number: Page 10 of 20
Function: Regulatory Affairs	Effective Date: July 9, 2025	Version number: 4.0

Section 11. Toxicological information

Conclusion/Summary [Product] : Not available.

Skin corrosion/irritation

Product/ingredient name

Castor oil

Result

Guinea pig - Skin - Mild irritant

Duration of treatment/exposure: 24 hours

Amount/concentration applied: 100 mg

Rat - Skin - Mild irritant

Duration of treatment/exposure: 24 hours

Amount/concentration applied: 100 mg

benzyl alcohol

Rabbit - Skin - Moderate irritant

Duration of treatment/exposure: 24 hours

Amount/concentration applied: 100 mg

Conclusion/Summary [Product] : Not available.

Serious eye damage/eye irritation

Product/ingredient name

Castor oil

Result

Rabbit - Eyes - Mild irritant

Amount/concentration applied: 500 mg

Rabbit - Eyes - Mild irritant

Duration of treatment/exposure: 24 hours

Amount/concentration applied: 500 mg

Rabbit - Eyes - Moderate irritant

Duration of treatment/exposure:

0.066666667 minutes

Amount/concentration applied: 100 mg

Rabbit - Eyes - Moderate irritant

Amount/concentration applied: 100 uL

Rabbit - Eyes - Severe irritant

Amount/concentration applied: 500 mg

Rabbit - Eyes - Mild irritant

Duration of treatment/exposure: 1 hours

Amount/concentration applied: 50 pph

Conclusion/Summary [Product] : Not available.

Respiratory corrosion/irritation



SDS Title: Fulvestrant Injection Safety Data Sheet	SDS Number: SDS-000019	Page Number: Page 11 of 20
Function: Regulatory Affairs	Effective Date: July 9, 2025	Version number: 4.0

Section 11. Toxicological information

Conclusion/Summary [Product] : Not available.

Respiratory or skin sensitization

Skin

Conclusion/Summary [Product] : Not available.

Respiratory

Conclusion/Summary [Product] : Not available.

Germ cell mutagenicity

Conclusion/Summary [Product] : Not available.

Carcinogenicity

Conclusion/Summary [Product] : Not available.

Reproductive toxicity

Conclusion/Summary [Product] : Not available.

Specific target organ toxicity (single exposure)

Product/ingredient name

Ethanol

benzyl alcohol

Result

SPECIFIC TARGET ORGAN TOXICITY (SINGLE EXPOSURE)
(Narcotic effects) - Category 3

SPECIFIC TARGET ORGAN TOXICITY (SINGLE EXPOSURE)
(Respiratory tract irritation) - Category 3

Specific target organ toxicity (repeated exposure)

Product/ingredient name

Ethanol

Result

SPECIFIC TARGET ORGAN TOXICITY (REPEATED EXPOSURE)
(liver) - Category 2

Aspiration hazard

Not available.

Information on the likely routes of exposure



SDS Title: Fulvestrant Injection Safety Data Sheet	SDS Number: SDS-000019	Page Number: Page 12 of 20
Function: Regulatory Affairs	Effective Date: July 9, 2025	Version number: 4.0

Section 11. Toxicological information

Routes of entry anticipated: Oral, Dermal, Inhalation, Eyes.

Potential acute health effects

- Eye contact** : Causes serious eye irritation.
- Inhalation** : No known significant effects or critical hazards.
- Skin contact** : Causes skin irritation. May cause an allergic skin reaction.
- Ingestion** : No known significant effects or critical hazards.

Symptoms related to the physical, chemical and toxicological characteristics

- Eye contact** : Adverse symptoms may include the following:
pain or irritation
watering
redness
- Inhalation** : Adverse symptoms may include the following:
reduced fetal weight
increase in fetal deaths
skeletal malformations
- Skin contact** : Adverse symptoms may include the following:
irritation
redness
reduced fetal weight
increase in fetal deaths
skeletal malformations
- Ingestion** : Adverse symptoms may include the following:
reduced fetal weight
increase in fetal deaths
skeletal malformations

Delayed and immediate effects and also chronic effects from short and long term exposure

Short term exposure

Potential immediate effects : Not available.

Potential delayed effects : Not available.

Long term exposure

Potential immediate effects : Not available.

Potential delayed effects : Not available.

Potential chronic health effects

Conclusion/Summary [Product] : Not available.

SDS Title: Fulvestrant Injection Safety Data Sheet	SDS Number: SDS-000019	Page Number: Page 13 of 20
Function: Regulatory Affairs	Effective Date: July 9, 2025	Version number: 4.0

Section 11. Toxicological information

- General** : May cause damage to organs through prolonged or repeated exposure. Once sensitized, a severe allergic reaction may occur when subsequently exposed to very low levels.
- Carcinogenicity** : No known significant effects or critical hazards.
- Mutagenicity** : No known significant effects or critical hazards.
- Reproductive toxicity** : May damage fertility or the unborn child.
May cause harm to breast-fed children.

Numerical measures of toxicity

Acute toxicity estimates

Product/ingredient name	Oral (mg/kg)	Dermal (mg/kg)	Inhalation (gases) (ppm)	Inhalation (vapors) (mg/l)	Inhalation (dusts and mists) (mg/l)
Fulvestrant Injection	5904.3	2868.6	N/A	N/A	N/A
Castor oil	10000	N/A	N/A	N/A	N/A
benzyl benzoate	1700	4000	N/A	N/A	N/A
Ethanol	7000	N/A	N/A	124.7	N/A
benzyl alcohol	1230	2000	N/A	N/A	N/A

Section 12. Ecological information

Toxicity

Product/ingredient name	Result	
benzyl benzoate	Acute - LC50 - Fresh water	<u>Effect:</u> Mortality
	Fish - Rainbow trout, donaldson trout - <i>Oncorhynchus mykiss</i>	US EPA
	<u>Weight:</u> 1.8 g	
	1.4 ppm [96 hours]	
	Acute - EC50 - Fresh water	OECD [Daphnia sp. Acute Immobilization Test and Reproduction Test]
	Daphnia	
3.09 mg/l [48 hours]		
Chronic - NOEC - Fresh water	OECD [Daphnia Magna Reproduction Test]	
Daphnia		
0.258 mg/l [21 days]		
Acute - NOEC - Fresh water	OECD [Alga, Growth Inhibition Test]	
Algae		
0.065 mg/l [72 hours]		
Chronic - NOEC - Fresh water	OECD [Fish, Early-Life Stage Toxicity Test]	
Fish		
0.023 mg/l [35 days]		
Acute - EC50 - Fresh water	OECD [Alga, Growth Inhibition Test]	
Algae		
0.311 mg/l [72 hours]		

SDS Title: Fulvestrant Injection Safety Data Sheet	SDS Number: SDS-000019	Page Number: Page 14 of 20
Function: Regulatory Affairs	Effective Date: July 9, 2025	Version number: 4.0

Section 12. Ecological information

Ethanol	Acute - LC50 - Fresh water	<u>Effect:</u> Mortality
	Fish - Rainbow trout, donaldson trout - <i>Oncorhynchus mykiss</i>	
	42 mg/l [4 days]	
	Acute - EC50 - Marine water	<u>Effect:</u> Reproduction
	Algae - Green algae - <i>Ulva pertusa</i>	
	17.921 mg/l [96 hours]	
	Chronic - NOEC - Marine water	<u>Effect:</u> Reproduction
	Algae - Green algae - <i>Ulva pertusa</i>	
	4.995 mg/l [96 hours]	
	Chronic - NOEC - Fresh water	<u>Effect:</u> Mortality
Daphnia - Water flea - <i>Daphnia magna</i> - Neonate		
<u>Age:</u> <24 hours		
100 µl/l [21 days]		
Chronic - NOEC - Fresh water	<u>Effect:</u> Morphology	
Fish - Eastern mosquitofish - <i>Gambusia holbrooki</i> - Larvae		
<u>Age:</u> 3 days		
0.375 µl/l [12 weeks]		
Acute - EC50 - Fresh water	<u>Effect:</u> Intoxication	
Daphnia - Water flea - <i>Daphnia magna</i>		
2 mg/l [48 hours]		
benzyl alcohol	Acute - LC50 - Fresh water	<u>Effect:</u> Mortality
	Fish - Bluegill - <i>Lepomis macrochirus</i>	
	10 ppm [96 hours]	
	Acute - EC50 - Fresh water	OECD [Daphnia sp. Acute Immobilization Test and Reproduction Test]
	Daphnia	
	230 mg/l [48 hours]	
	Chronic - NOEC - Fresh water	OECD [Daphnia Magna Reproduction Test]
	Daphnia	
	51 mg/l [21 days]	
	Acute - EC50 - Fresh water	OECD [Alga, Growth Inhibition Test]
Algae		
495 mg/l [72 hours]		
Acute - NOEC - Fresh water	OECD [Alga, Growth Inhibition Test]	
Algae		
309 mg/l [72 hours]		
fulvestrant	Chronic - NOEC - Fresh water	<u>Effect:</u> Hormones US EPA
	Daphnia - Water flea - <i>Daphnia magna</i>	
	<u>Age:</u> <24 hours	
	100 µg/l [21 days]	
	Chronic - NOEC - Fresh water	<u>Effect:</u> Development US EPA
	Fish - Medaka, high-eyes - <i>Oryzias latipes</i> - Larvae	
<u>Age:</u> 8 days		
0.3 mg/l [30 days]		

SDS Title: Fulvestrant Injection Safety Data Sheet	SDS Number: SDS-000019	Page Number: Page 15 of 20
Function: Regulatory Affairs	Effective Date: July 9, 2025	Version number: 4.0

Section 12. Ecological information

Conclusion/Summary [Product] : Not available.

Persistence and degradability

Product/ingredient name	Result	EU
benzyl benzoate	Aerobic 94% [28 days] - Readily	

Conclusion/Summary [Product] : Not available.

Product/ingredient name	Aquatic half-life	Photolysis	Biodegradability
benzyl benzoate	-	-	Readily
Ethanol	-	-	Readily
benzyl alcohol	-	-	Readily

Bioaccumulative potential

Product/ingredient name	LogP _{ow}	BCF	Potential
benzyl benzoate	3.97	-	Low
Ethanol	-0.35	-	Low
benzyl alcohol	0.87	-	Low
fulvestrant	8.9	-	High
nitrogen	0.67	-	Low

Mobility in soil

Soil/Water partition coefficient : Not available.

Other adverse effects

No known significant effects or critical hazards.

Section 13. Disposal considerations






Disposal methods : The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible. This material and its container must be disposed of in a safe way. Care should be taken when handling emptied containers that have not been cleaned or rinsed out. Empty containers or liners may retain some product residues. Vapor from product residues may create a highly flammable or explosive atmosphere inside the container. Do not cut, weld or grind used containers unless they have been cleaned thoroughly internally. Avoid dispersal of spilled material and runoff and contact

SDS Title: Fulvestrant Injection Safety Data Sheet	SDS Number: SDS-000019	Page Number: Page 16 of 20
Function: Regulatory Affairs	Effective Date: July 9, 2025	Version number: 4.0

Section 13. Disposal considerations

with soil, waterways, drains and sewers.

Section 14. Transport information

	DOT Classification	IMDG	IATA
UN number	UN1993	UN1993	UN1993
UN proper shipping name	Flammable liquids, n.o.s. (Ethanol)	FLAMMABLE LIQUID, N.O.S. (Ethanol)	Flammable liquid, n.o.s. (Ethanol)
Transport hazard class(es)	3  	3  	3 
Packing group	III	III	III
Environmental hazards	Yes.	Yes.	Yes. The environmentally hazardous substance mark is not required.

Additional information

DOT Classification

: This product may be re-classified as "Combustible Liquid," unless transported by vessel or aircraft. Non-bulk packages (less than or equal to 119 gal) of combustible liquids, that are marine pollutants, are not regulated as hazardous materials, unless transported by vessel.

This product is not regulated as a marine pollutant when transported on inland waterways in sizes of ≤5 L or ≤5 kg or by road, rail, or inland air in non-bulk sizes, provided the packagings meet the general provisions of §§ 173.24 and 173.24a.

Limited quantity Yes.

Packaging instruction Exceptions: 150. Non-bulk: 203. Bulk: 242.

Quantity limitation Passenger aircraft/rail: 60 L. Cargo aircraft: 220 L.

Special provisions B1, B52, IB3, T4, TP1, TP29

IMDG

: The marine pollutant mark is not required when transported in sizes of ≤5 L or ≤5 kg.

Emergency schedules F-E, _S-E_

Special provisions 223, 274, 955

IATA

: The environmentally hazardous substance mark may appear if required by other transportation regulations.

Quantity limitation Passenger and Cargo Aircraft: 60 L. Packaging instructions: 355.

Cargo Aircraft Only: 220 L. Packaging instructions: 366. Limited Quantities - Passenger Aircraft: 10 L. Packaging instructions: Y344.

Special provisions A3

Special precautions for user : **Transport within user's premises:** always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.



SDS Title: Fulvestrant Injection Safety Data Sheet	SDS Number: SDS-000019	Page Number: Page 17 of 20
Function: Regulatory Affairs	Effective Date: July 9, 2025	Version number: 4.0

Section 14. Transport information

Transport in bulk according to IMO instruments : Not available.

Section 15. Regulatory information

U.S. Federal regulations : **TSCA 8(a) CDR Exempt/Partial exemption:** Not determined
United States inventory (TSCA 8b): Not determined.

TSCA 12(b) - Chemical export notification

Not applicable.

Clean Air Act Section 112 (b) Hazardous Air Pollutants (HAPs) : Not listed

Clean Air Act Section 602 Class I Substances : Not listed

Clean Air Act Section 602 Class II Substances : Not listed

DEA List I Chemicals (Precursor Chemicals) : Not listed

DEA List II Chemicals (Essential Chemicals) : Not listed

SARA 302/304

Composition/information on ingredients

No products were found.

SARA 304 RQ : Not applicable.

SARA 311/312

Classification : FLAMMABLE LIQUIDS - Category 3
SKIN IRRITATION - Category 2
EYE IRRITATION - Category 2A
SKIN SENSITIZATION - Category 1
TOXIC TO REPRODUCTION - Category 1B
TOXIC TO REPRODUCTION - Effects on or via lactation
SPECIFIC TARGET ORGAN TOXICITY (REPEATED EXPOSURE) - Category 2

Composition/information on ingredients

SDS Title: Fulvestrant Injection Safety Data Sheet	SDS Number: SDS-000019	Page Number: Page 18 of 20
Function: Regulatory Affairs	Effective Date: July 9, 2025	Version number: 4.0

Section 15. Regulatory information

Name	%	Classification
Castor oil	≥60 - ≤80	EYE IRRITATION - Category 2B
benzyl benzoate	≥10 - ≤30	ACUTE TOXICITY (oral) - Category 4
Ethanol	≥7 - ≤13	FLAMMABLE LIQUIDS - Category 2 EYE IRRITATION - Category 2A SPECIFIC TARGET ORGAN TOXICITY (SINGLE EXPOSURE) (Narcotic effects) - Category 3 SPECIFIC TARGET ORGAN TOXICITY (REPEATED EXPOSURE) - Category 2 HNOC - Defatting irritant
benzyl alcohol	≥7 - ≤13	ACUTE TOXICITY (oral) - Category 4 ACUTE TOXICITY (dermal) - Category 4 SKIN IRRITATION - Category 2 EYE IRRITATION - Category 2A SKIN SENSITIZATION - Category 1B SPECIFIC TARGET ORGAN TOXICITY (SINGLE EXPOSURE) (Respiratory tract irritation) - Category 3
fulvestrant	≥3 - ≤7	TOXIC TO REPRODUCTION - Category 1B
nitrogen	≥0.1 - ≤1	TOXIC TO REPRODUCTION - Effects on or via lactation GASES UNDER PRESSURE - Compressed gas SIMPLE ASPHYXIANTS

SARA 313

Not applicable.

State regulations

- Massachusetts** : The following components are listed: ETHYL ALCOHOL; BENZYL ALCOHOL
- New York** : None of the components are listed.
- New Jersey** : The following components are listed: ETHYL ALCOHOL
- Pennsylvania** : The following components are listed: ETHANOL; BENZENEMETHANOL

California Prop. 65

This product does not require a Safe Harbor warning under California Prop. 65.

International regulations

Chemical Weapon Convention List Schedules I, II & III Chemicals

Not listed.

Montreal Protocol

Not listed.

Stockholm Convention on Persistent Organic Pollutants

Not listed.

Rotterdam Convention on Prior Informed Consent (PIC)

Not listed.

UNECE Aarhus Protocol on POPs and Heavy Metals

SDS Title: Fulvestrant Injection Safety Data Sheet	SDS Number: SDS-000019	Page Number: Page 19 of 20
Function: Regulatory Affairs	Effective Date: July 9, 2025	Version number: 4.0

Section 15. Regulatory information

Not listed.

Section 16. Other information

Hazardous Material Information System (U.S.A.)

Health	*	4
Flammability		2
Physical hazards		0

Caution: HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. Although HMIS® ratings and the associated label are not required on SDSs or products leaving a facility under 29 CFR 1910.1200, the preparer may choose to provide them. HMIS® ratings are to be used with a fully implemented HMIS® program. HMIS® is a registered trademark and service mark of the American Coatings Association, Inc.

The customer is responsible for determining the PPE code for this material. For more information on HMIS® Personal Protective Equipment (PPE) codes, consult the HMIS® Implementation Manual.

National Fire Protection Association (U.S.A.)



Procedure used to derive the classification

Classification	Justification
FLAMMABLE LIQUIDS - Category 3	On basis of test data
SKIN IRRITATION - Category 2	Calculation method
EYE IRRITATION - Category 2A	Calculation method
SKIN SENSITIZATION - Category 1	Calculation method
TOXIC TO REPRODUCTION - Category 1B	Calculation method
TOXIC TO REPRODUCTION - Effects on or via lactation	Calculation method
SPECIFIC TARGET ORGAN TOXICITY (REPEATED EXPOSURE) - Category 2	Calculation method

History

Date of issue/Date of revision	: 07/09/2025
Date of previous issue	: 07/24/2023
Version	: 4.0
Prepared by	: Sphera Solutions



SDS Title: Fulvestrant Injection Safety Data Sheet	SDS Number: SDS-000019	Page Number: Page 20 of 20
Function: Regulatory Affairs	Effective Date: July 9, 2025	Version number: 4.0

Section 16. Other information

Key to abbreviations

- : ATE = Acute Toxicity Estimate
- BCF = Bioconcentration Factor
- GHS = Globally Harmonized System of Classification and Labelling of Chemicals
- IATA = International Air Transport Association
- IBC = Intermediate Bulk Container
- IMDG = International Maritime Dangerous Goods
- IMO = International Maritime Organization
- LogPow = logarithm of the octanol/water partition coefficient
- MARPOL = International Convention for the Prevention of Pollution From Ships, 1973 as modified by the Protocol of 1978. ("Marpol" = marine pollution)
- N/A = Not available
- SGG = Segregation Group
- TDG = Transportation of Dangerous Goods
- UN = United Nations

References

- : HCS (U.S.A.)- Hazard Communication Standard
- International transport regulations

📌 Indicates information that has changed from previously issued version.

Notice to reader

To the best of our knowledge, the information contained herein is accurate. However, neither the above-named supplier, nor any of its subsidiaries, assumes any liability whatsoever for the accuracy or completeness of the information contained herein.

Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.