



SDS Title: Fulvestrant Injection Safety Data Sheet	SDS Number: SDS-000019	Page Number: Page 1 of 18
Function: Regulatory Affairs	Effective Date: July 26, 2021	Version number: 2.0

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
H332 ACUTE TOXICITY (inhalation) - Category 4
H315 SKIN IRRITATION - Category 2
H319 EYE IRRITATION - Category 2A
H360 TOXIC TO REPRODUCTION - Category 1B
H362 TOXIC TO REPRODUCTION - Effects on or via lactation
H373 SPECIFIC TARGET ORGAN TOXICITY (REPEATED EXPOSURE) - Category 2

Percentage of the mixture consisting of ingredient(s) of unknown acute inhalation toxicity: 80%

GHS label elements

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Section 2. Hazards identification

Hazard pictograms



Signal word

: Danger

Hazard statements

: H226 - Flammable liquid and vapor.
 H315 - Causes skin irritation.
 H319 - Causes serious eye irritation.
 H332 - Harmful if inhaled.
 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.
 P241 - Use explosion-proof electrical, ventilating or lighting equipment.
 P242 - Use non-sparking tools.
 P243 - Take action to prevent static discharges.
 P233 - Keep container tightly closed.
 P271 - Use only outdoors or in a well-ventilated area.
 P260 - Do not breathe vapor.
 P263 - Avoid contact during pregnancy or while nursing.
 P270 - Do not eat, drink or smoke when using this product.
 P264 - Wash thoroughly after handling.

Response

: P308 + P313 - IF exposed or concerned: Get medical advice or attention.
 P304 + P340, P312 - IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER or doctor if you feel unwell.
 P303 + P361 + P353 - IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.
 P302 + P352 - IF ON SKIN: Wash with plenty of water.
 P332 + P313 - If skin irritation 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.
 P403 + P235 - Store in a well-ventilated place. Keep cool.

Disposal

: P501 - Dispose of contents and container in accordance with all local, regional, national and international regulations.

Hazards not otherwise classified

: None known.

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Section 3. Composition/information on ingredients

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

Ingredient name	Other names	%	CAS number
Castor oil	-	≥50 - ≤75	8001-79-4
benzyl benzoate	-	≥10 - ≤15	120-51-4
Ethanol	-	≥10 - ≤25	64-17-5
benzyl alcohol	-	≥10 - ≤25	100-51-6
fulvestrant	-	≤10	129453-61-8
nitrogen	-	≤0.3	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 as hazardous to health 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 it is suspected that fumes are still present, the rescuer should wear an appropriate mask or self-contained breathing apparatus. 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 necessary, call a poison center or physician. 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** : Flush contaminated skin with plenty of 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. 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.



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Section 4. First aid measures

Most important symptoms/effects, acute and delayed

Potential acute health effects

- Eye contact** : Causes serious eye irritation.
- Inhalation** : Harmful if inhaled.
- Skin contact** : Causes skin irritation.
- 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)



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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.

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

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Section 6. Accidental release measures

- Small spill** : Stop leak if without risk. Move containers from spill area. Use spark-proof tools and explosion-proof equipment. Dilute with water and mop up if water-soluble. Alternatively, or if water-insoluble, absorb with an inert dry 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. 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 (see Section 13). Dispose of via a licensed waste disposal contractor. Contaminated absorbent material may pose the same hazard as the spilled product. Note: see Section 1 for emergency contact information and Section 13 for waste disposal.

Section 7. Handling and storage

Precautions for safe handling

- Protective measures** : Put on appropriate personal protective equipment (see Section 8). 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.

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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, 3/2020). STEL: 1000 ppm 15 minutes. NIOSH REL (United States, 10/2016). TWA: 1000 ppm 10 hours. TWA: 1900 mg/m ³ 10 hours. OSHA PEL (United States, 5/2018). TWA: 1000 ppm 8 hours. TWA: 1900 mg/m ³ 8 hours.
benzyl alcohol	OARS WEEL (United States, 7/2020). TWA: 10 ppm 8 hours.
fulvestrant nitrogen	None. ACGIH TLV (United States, 3/2020). Oxygen Depletion [Asphyxiant].

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. 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



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Section 8. Exposure controls/personal 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.
- 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

Appearance

- Physical state** : Liquid. [Viscous]
- Color** : Colorless./Yellow.
- Odor** : Odorless.
- Odor threshold** : Not available.
- pH** : Not applicable.
- Melting point** : Not applicable.
- Boiling point** : 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 (solid, gas)** : Not applicable.
- Lower and upper explosive (flammable) limits** : Not applicable.
- Vapor pressure** : Not applicable.
- Vapor density** : Not available.
- Relative density** : 0.983 [Water = 1]
- Density** : 0.983 g/cm³ [25°C (77°F)]
- Solubility** : Not available.
- Solubility in water** : Not available.



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Section 9. Physical and chemical properties

- 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.
- Flow time (ISO 2431)** : Not available.

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



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Section 11. Toxicological information

Product/ingredient name	Result	Species	Dose	Exposure
Castor oil	LD50 Oral	Rat	10 g/kg	-
	LD50 Dermal	Rabbit	4 g/kg	-
benzyl benzoate	LD50 Oral	Rat	2800 mg/kg	-
	LC50 Inhalation Vapor	Rat	124700 mg/m ³	4 hours
Ethanol	LD50 Oral	Rat	7 g/kg	-
	LC50 Inhalation Dusts and mists	Rat - Male, Female	>4178 mg/m ³	4 hours
benzyl alcohol	LD50 Dermal	Rabbit	2000 mg/kg	-
	LD50 Oral	Rat	1230 mg/kg	-

Irritation/Corrosion

Product/ingredient name	Result	Species	Score	Exposure	Observation
Castor oil	Eyes - Mild irritant	Rabbit	-	500 milligrams	-
	Skin - Mild irritant	Guinea pig	-	24 hours 100 mg	-
	Skin - Mild irritant	Rat	-	24 hours 100 mg	-
Ethanol	Eyes - Mild irritant	Rabbit	-	24 hours 500 mg	-
	Eyes - Moderate irritant	Rabbit	-	0.066666667 minutes 100 mg	-
benzyl alcohol	Eyes - Moderate irritant	Rabbit	-	100 uL	-
	Eyes - Severe irritant	Rabbit	-	500 mg	-
	Skin - Moderate irritant	Rabbit	-	24 hours 100 milligrams	-

Sensitization

Not available.

Mutagenicity

Conclusion/Summary : Not available.

Carcinogenicity

Conclusion/Summary : Not available.

Reproductive toxicity

Conclusion/Summary : Not available.

Teratogenicity

Conclusion/Summary : Not available.

Specific target organ toxicity (single exposure)



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Name	Category	Route of exposure	Target organs
Ethanol	Category 3	-	Narcotic effects
benzyl alcohol	Category 3	-	Respiratory tract irritation

Specific target organ toxicity (repeated exposure)

Name	Category	Route of exposure	Target organs
Ethanol	Category 2	-	liver

Aspiration hazard

Not available.

Information on the likely routes of exposure : Routes of entry anticipated: Oral, Dermal, Inhalation.

Potential acute health effects

- Eye contact** : Causes serious eye irritation.
- Inhalation** : Harmful if inhaled.
- Skin contact** : Causes skin irritation.
- 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

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Section 11. Toxicological information

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

Not available.

General : May cause damage to organs through prolonged or repeated exposure.

Carcinogenicity : No known significant effects or critical hazards.

Mutagenicity : No known significant effects or critical hazards.

Teratogenicity : May damage the unborn child.

Developmental effects : May cause harm to breast-fed children.

Fertility effects : Suspected of damaging fertility.

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	2625.2	2868.6	N/A	N/A	3
Castor oil	10000	N/A	N/A	N/A	N/A
benzyl benzoate	500	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	1.5

Section 12. Ecological information

Toxicity

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Product/ingredient name	Result	Species	Exposure
benzyl benzoate Ethanol	NOEC 0.065 mg/l Fresh water	Algae	72 hours
	Acute EC50 3.09 mg/l Fresh water	Daphnia	48 hours
	Acute LC50 1.4 ppm Fresh water	Fish - Oncorhynchus mykiss	96 hours
	Chronic NOEC 0.258 mg/l Fresh water	Daphnia	21 days
	Acute EC50 17.921 mg/l Marine water	Algae - Ulva pertusa	96 hours
	Acute EC50 2000 µg/l Fresh water	Daphnia - Daphnia magna	48 hours
	Acute LC50 25500 µg/l Marine water	Crustaceans - Artemia franciscana - Larvae	48 hours
	Acute LC50 42000 µg/l Fresh water	Fish - Oncorhynchus mykiss	4 days
	Chronic NOEC 4.995 mg/l Marine water	Algae - Ulva pertusa	96 hours
	Chronic NOEC 100 ul/L Fresh water	Daphnia - Daphnia magna - Neonate	21 days
benzyl alcohol fulvestrant	Chronic NOEC 0.375 ul/L Fresh water	Fish - Gambusia holbrooki - Larvae	12 weeks
	Acute LC50 10000 µg/l Fresh water	Fish - Lepomis macrochirus	96 hours
	Chronic NOEC 100 µg/l Fresh water	Daphnia - Daphnia magna	21 days

Conclusion/Summary : Not available.

Persistence and degradability

Product/ingredient name	Test	Result	Dose	Inoculum
benzyl benzoate	EU	94 % - Readily - 28 days	-	Activated sludge

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
Castor oil	19.8	-	high
benzyl benzoate	3.97	-	low
Ethanol	-0.35	-	low
benzyl alcohol	0.87	-	low
fulvestrant	9.09	-	high
nitrogen	0.67	-	low

Mobility in soil

Soil/water partition coefficient (K_{oc}) : Not available.




Other adverse effects : No known significant effects or critical hazards.

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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 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	No.	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 are not regulated as hazardous materials.

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

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Section 14. Transport information

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.

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.

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
 ACUTE TOXICITY (inhalation) - Category 4
 SKIN IRRITATION - Category 2
 EYE IRRITATION - Category 2A
 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

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Section 15. Regulatory information

Name	%	Classification
Castor oil	≥50 - ≤75	EYE IRRITATION - Category 2B
benzyl benzoate	≥10 - ≤15	ACUTE TOXICITY (oral) - Category 4
Ethanol	≥10 - <20	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	≤10	FLAMMABLE LIQUIDS - Category 4 ACUTE TOXICITY (oral) - Category 4 ACUTE TOXICITY (dermal) - Category 4 ACUTE TOXICITY (inhalation) - Category 4 SKIN IRRITATION - Category 2 EYE IRRITATION - Category 2A SPECIFIC TARGET ORGAN TOXICITY (SINGLE EXPOSURE) (Respiratory tract irritation) - Category 3
fulvestrant	≤10	TOXIC TO REPRODUCTION - Category 1B
nitrogen	≤0.3	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; ETHANOL; DENATURED ALCOHOL; BENZYL ALCOHOL

New York

: None of the components are listed.

New Jersey

: The following components are listed: ETHYL ALCOHOL; METHYLCARBINOL; ETHANOL; ALCOHOL

Pennsylvania

: The following components are listed: DENATURED ALCOHOL; 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.

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Rotterdam Convention on Prior Informed Consent (PIC)

Not listed.

UNECE Aarhus Protocol on POPs and Heavy Metals

Not listed.

Section 16. Other information

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

Health	*	4
Flammability		2
Physical hazards		0

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



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Copyright ©2001, National Fire Protection Association, Quincy, MA 02269. This warning system is intended to be interpreted and applied only by properly trained individuals to identify fire, health and reactivity hazards of chemicals. The user is referred to certain limited number of chemicals with recommended classifications in NFPA 49 and NFPA 325, which would be used as a guideline only. Whether the chemicals are classified by NFPA or not, anyone using the 704 systems to classify chemicals does so at their own risk.

Procedure used to derive the classification



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Section 16. Other information

Classification	Justification
FLAMMABLE LIQUIDS - Category 3 ACUTE TOXICITY (inhalation) - Category 4 SKIN IRRITATION - Category 2 EYE IRRITATION - Category 2A TOXIC TO REPRODUCTION - Category 1B TOXIC TO REPRODUCTION - Effects on or via lactation SPECIFIC TARGET ORGAN TOXICITY (REPEATED EXPOSURE) - Category 2	On basis of test data Calculation method Calculation method Calculation method Calculation method Calculation method Calculation method

History

Date of issue/Date of revision	: 07/26/2021
Date of previous issue	: 01/08/2020
Version	: 2.0
Prepared by	: Sphera Solutions
Key to abbreviations	: ATE = Acute Toxicity Estimate AMP = Acceptable maximum peak above the acceptable ceiling concentration for an 8-hr shift 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 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 UN = United Nations
References	: HCS (U.S.A.)- Hazard Communication Standard International transport regulations

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