

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Form: Mixture

Product Name: Estradiol Valerate Injection, USP 20 mg/mL, 40mg/mL

Product Code: 0517-0420-01; 0517-0440-01

1.2. Intended Use of the Product

- Use of the Substance/Mixture:**
1. Treatment of moderate to severe vasomotor symptoms associated with the menopause.
 2. Treatment of moderate to severe symptoms of vulvar and vaginal atrophy associated with the menopause. When prescribing solely for the treatment of symptoms of vulvar and vaginal atrophy, topical vaginal products should be considered.
 3. Treatment of hypoestrogenism due to hypogonadism, castration or primary ovarian failure.
 4. Treatment of advanced androgen-dependent carcinoma of the prostate (for palliation only).

1.3. Name, Address, and Telephone of the Responsible Party

Company

American Regent
5 Ramsey Road
Shirley NY, 11967
1-800-645-1706

<http://www.americanregent.com/>

1.4. Emergency Telephone Number

Emergency Number : 1-800-424-9300 (CHEMTREC)

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the Substance or Mixture

Acute Tox. 4 (Oral)	H302
Carc. 1A	H350
Repr. 1B	H360
Aquatic Acute 1	H400
Aquatic Chronic 2	H411

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

2.2. Label Elements

GHS-US Labeling

Hazard Pictograms (GHS-US)



Signal Word (GHS-US)

: Danger

Hazard Statements (GHS-US)

- : H302 - Harmful if swallowed.
H350 - May cause cancer.
H360 - May damage fertility or the unborn child.
H400 - Very toxic to aquatic life.
H411 - Toxic to aquatic life with long lasting effects.

Precautionary Statements (GHS-US)

- : P201 - Obtain special instructions before use.
P202 - Do not handle until all safety precautions have been read and understood.
P264 - Wash hands, forearms, and other exposed areas thoroughly after handling.
P270 - Do not eat, drink or smoke when using this product.
P273 - Avoid release to the environment.
P280 - Wear protective gloves, protective clothing, and eye protection.
P301+P312 - If swallowed: Call a poison center or doctor if you feel unwell.
P308+P313 - If exposed or concerned: Get medical advice/attention.
P330 - Rinse mouth.
P391 - Collect spillage.
P405 - Store locked up.
P501 - Dispose of contents/container in accordance with local, regional, national, and international regulations.

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2.3. Other Hazards

Exposure may aggravate pre-existing eye, skin, or respiratory conditions.

2.4. Unknown Acute Toxicity (GHS-US)

No data available

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substance

Not applicable

3.2. Mixture

Name	Synonyms	Product Identifier	%	GHS US classification
Castor oil	Oils, castor / Castor oil extractives and physically modified derivatives obtained from Ricinus communis, Euphorbiaceae (Physeter) / RICINUS COMMUNIS OIL / Ricinus communis L. / Castor oil (Ricinus communis L.) / Castor oil (Extractives and their physically modified derivatives. It consists primarily of the glycerides of the fatty acid ricinoleic. (Ricinus communis).) / RICINUS COMMUNIS (CASTOR) ROOT EXTRACT	(CAS-No.) 8001-79-4	49.3 - 73.6	Not classified
Benzyl benzoate	Benzoate, benzyl / Benzoic acid, benzyl ester / Benzoic acid, phenylmethyl ester / BENZYL BENZOATE	(CAS-No.) 120-51-4	22.4 - 44.7	Acute Tox. 4 (Oral), H302 Aquatic Acute 1, H400 Aquatic Chronic 2, H411
Estradiol valerate	Estradiol, 17-valerate / Estra-1,3,5(10)-triene-3,17-diol (17.beta.-), 17-pentanoate / Oestradiol valerate / Oestradiol-17b-valerate	(CAS-No.) 979-32-8	2 - 4	Carc. 1A, H350 Repr. 1B, H360
Benzyl alcohol	Benzenecarbinol / Benzenemethanol / Methanol, phenyl- / Phenylmethanol / Phenylmethyl alcohol / BENZYL ALCOHOL / .alpha.-Hydroxytoluene	(CAS-No.) 100-51-6	2	Flam. Liq. 4, H227 Acute Tox. 4 (Oral), H302 Acute Tox. 4 (Inhalation:dust,mist), H332 Eye Irrit. 2A, H319 Aquatic Acute 2, H401

Full text of H-phrases: see section 16

SECTION 4: FIRST AID MEASURES

4.1. Description of First-aid Measures

First-aid Measures General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

First-aid Measures After Inhalation: When symptoms occur: go into open air and ventilate suspected area. Obtain medical attention if breathing difficulty persists.

First-aid Measures After Skin Contact: Remove contaminated clothing. Drench affected area with water for several minutes. Obtain medical attention if irritation develops or persists.

First-aid Measures After Eye Contact: Rinse cautiously with water for at least 5 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention if irritation develops or persists.

First-aid Measures After Ingestion: Rinse mouth. Do NOT induce vomiting. Obtain medical attention.

4.2. Most Important Symptoms and Effects Both Acute and Delayed

Symptoms/Injuries: Harmful if swallowed. May cause cancer. May damage fertility. May damage the unborn child.

Symptoms/Injuries After Inhalation: Prolonged exposure may cause irritation.

Symptoms/Injuries After Skin Contact: Prolonged exposure may cause skin irritation.

Symptoms/Injuries After Eye Contact: May cause slight irritation to eyes.

Symptoms/Injuries After Ingestion: This material is harmful orally and can cause adverse health effects or death in significant amounts.

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Chronic Symptoms: Many oestradiols are designated by IARC as a group 1 carcinogen. Under normal workplace conditions the carcinogenic and reproductive toxicity potential of these products is low. However, if exposed to therapeutic doses over prolonged periods, oestradiols may damage fertility or the unborn child and may cause cancer. Oestradiols are linked to increased risk of cancers including endometrial, breast, and ovarian cancers. Effects on or via lactation are inconclusive, however detectable amounts of estrogens have been identified in the milk of mothers receiving this drug.

4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

If exposed or concerned, get medical advice and attention. If medical advice is needed, have product container or label at hand.

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing Media

Suitable Extinguishing Media: Water spray, fog, carbon dioxide (CO₂), alcohol-resistant foam, or dry chemical.

Unsuitable Extinguishing Media: Do not use a heavy water stream. Use of heavy stream of water may spread fire.

5.2. Special Hazards Arising From the Substance or Mixture

Fire Hazard: Not considered flammable but may burn at high temperatures.

Explosion Hazard: Product is not explosive.

Reactivity: Hazardous reactions will not occur under normal conditions.

5.3. Advice for Firefighters

Precautionary Measures Fire: Exercise caution when fighting any chemical fire.

Firefighting Instructions: Use water spray or fog for cooling exposed containers. Do not breathe fumes from fires or vapors from decomposition.

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

Hazardous Combustion Products: Carbon oxides (CO, CO₂). Irritating fumes.

Other Information: Do not allow run-off from fire fighting to enter drains or water courses.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Do not breathe vapor, mist or spray. Do not get in eyes, on skin, or on clothing. Do not handle until all safety precautions have been read and understood.

6.1.1. For Non-Emergency Personnel

Protective Equipment: Use appropriate personal protective equipment (PPE).

Emergency Procedures: Evacuate unnecessary personnel.

6.1.2. For Emergency Personnel

Protective Equipment: Equip cleanup crew with proper protection.

Emergency Procedures: Upon arrival at the scene, a first responder is expected to recognize the presence of dangerous goods, protect oneself and the public, secure the area, and call for the assistance of trained personnel as soon as conditions permit. Ventilate area.

6.2. Environmental Precautions

Prevent entry to sewers and public waters. Avoid release to the environment. Collect spillage.

6.3. Methods and Materials for Containment and Cleaning Up

For Containment: Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams.

Methods for Cleaning Up: Clean up spills immediately and dispose of waste safely. Absorb and/or contain spill with inert material. Transfer spilled material to a suitable container for disposal. Contact competent authorities after a spill.

6.4. Reference to Other Sections

See Section 8 for exposure controls and personal protection and Section 13 for disposal considerations.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling

Additional Hazards When Processed: This SDS is for a pharmaceutical agent - Handling of this product in its final form presents minimal occupational exposure risk. In an occupational setting, handle in accordance with good industrial hygiene and safety procedures. Avoid contact with eyes, skin and clothing. Avoid breathing vapor or mist. Use appropriate personal protective equipment when handling and observe good personal hygiene measures after handling.

Precautions for Safe Handling: Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Do not breathe mist, spray, vapors. Do not get in eyes, on skin, or on clothing. Handle empty containers with care because they may still present a hazard. Use appropriate personal protective equipment (PPE).

Hygiene Measures: Handle in accordance with good industrial hygiene and safety procedures. Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reuse.

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7.2. Conditions for Safe Storage, Including Any Incompatibilities

Technical Measures: Comply with applicable regulations.

Storage Conditions: Keep container closed when not in use. Store in a dry, cool place. Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials. Store locked up/in a secure area.

Incompatible Materials: Strong acids, strong bases, strong oxidizers.

7.3. Specific End Use(s)

1. Treatment of moderate to severe vasomotor symptoms associated with the menopause.
2. Treatment of moderate to severe symptoms of vulvar and vaginal atrophy associated with the menopause. When prescribing solely for the treatment of symptoms of vulvar and vaginal atrophy, topical vaginal products should be considered.
3. Treatment of hypoenestrogenism due to hypogonadism, castration or primary ovarian failure.
4. Treatment of advanced androgen-dependent carcinoma of the prostate (for palliation only).

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control Parameters

For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), AIHA (WEEL), NIOSH (REL), or OSHA (PEL).

Benzyl alcohol (100-51-6)

USA AIHA	WEEL TWA (ppm)	10 ppm
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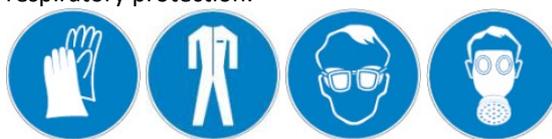
8.2. Exposure Controls

Appropriate Engineering Controls

: Suitable eye/body wash equipment should be available in the vicinity of any potential exposure. Ensure adequate ventilation, especially in confined areas. Ensure all national/local regulations are observed.

Personal Protective Equipment

: Gloves. Protective clothing. Protective goggles. Insufficient ventilation: wear respiratory protection.



Materials for Protective Clothing

: Chemically resistant materials and fabrics.

Hand Protection

: Wear protective gloves.

Eye and Face Protection

: Chemical safety goggles.

Skin and Body Protection

: Wear suitable protective clothing.

Respiratory Protection

: If exposure limits are exceeded or irritation is experienced, approved respiratory protection should be worn. In case of inadequate ventilation, oxygen deficient atmosphere, or where exposure levels are not known wear approved respiratory protection.

Other Information

: When using, do not eat, drink or smoke.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on Basic Physical and Chemical Properties

Physical State	: Liquid
Appearance	: Clear
Odor	: No data available
Odor Threshold	: No data available
pH	: No data available
Evaporation Rate	: No data available
Melting Point	: No data available
Freezing Point	: No data available
Boiling Point	: No data available
Flash Point	: No data available
Auto-ignition Temperature	: No data available
Decomposition Temperature	: No data available
Flammability (solid, gas)	: Not applicable
Vapor Pressure	: No data available
Relative Vapor Density at 20°C	: No data available
Relative Density	: No data available

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Solubility : Water: Insoluble
Partition Coefficient: N-Octanol/Water : No data available
Viscosity : No data available

9.2. Other Information No additional information available

SECTION 10: STABILITY AND REACTIVITY

- 10.1. Reactivity:** Hazardous reactions will not occur under normal conditions.
10.2. Chemical Stability: Stable under recommended handling and storage conditions (see section 7).
10.3. Possibility of Hazardous Reactions: Hazardous polymerization will not occur.
10.4. Conditions to Avoid: Direct sunlight, extremely high or low temperatures, and incompatible materials.
10.5. Incompatible Materials: Strong acids, strong bases, strong oxidizers.
10.6. Hazardous Decomposition Products: Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on Toxicological Effects

Acute Toxicity (Oral): Harmful if swallowed.

Acute Toxicity (Dermal): Not classified.

Acute Toxicity (Inhalation): Not classified.

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ATE (Oral)	1,098.59 mg/kg body weight
Benzyl benzoate (120-51-4)	
LD50 Oral Rat	500 mg/kg
LD50 Dermal Rabbit	4000 mg/kg
Benzyl alcohol (100-51-6)	
LD50 Oral Rat	1230 mg/kg
LD50 Dermal Rabbit	> 2000 mg/kg
LC50 Inhalation Rat	> 4.178 mg/l/4h
ATE (Dust/Mist)	1.50 mg/l/4h

Skin Corrosion/Irritation: Not classified.

Serious Eye Damage/Irritation: Not classified.

Respiratory or Skin Sensitization: Not classified.

Germ Cell Mutagenicity: Not classified.

Carcinogenicity: May cause cancer.

Estradiol valerate (979-32-8)	
IARC group	1
OSHA Hazard Communication Carcinogen List	In OSHA Hazard Communication Carcinogen list.

Reproductive Toxicity: May damage fertility or the unborn child.

Specific Target Organ Toxicity (Single Exposure): Not classified.

Specific Target Organ Toxicity (Repeated Exposure): Not classified.

Aspiration Hazard: Not classified.

Symptoms/Injuries After Inhalation: Prolonged exposure may cause irritation.

Symptoms/Injuries After Skin Contact: Prolonged exposure may cause skin irritation.

Symptoms/Injuries After Eye Contact: May cause slight irritation to eyes.

Symptoms/Injuries After Ingestion: This material is harmful orally and can cause adverse health effects or death in significant amounts.

Chronic Symptoms: Many oestradiols are designated by IARC as a group 1 carcinogen. Under normal workplace conditions the carcinogenic and reproductive toxicity potential of these products is low. However, if exposed to therapeutic doses over prolonged periods, oestradiols may damage fertility or the unborn child and may cause cancer. Oestradiols are linked to increased risk of cancers including endometrial, breast, and ovarian cancers. Effects on or via lactation are inconclusive, however detectable amounts of estrogens have been identified in the milk of mothers receiving this drug.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecology - General : Very toxic to aquatic life. Toxic to aquatic life with long lasting effects.

Benzyl benzoate (120-51-4)	
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LC50 Fish 1	0.29 mg/l
EC50 Daphnia 1	4.8 mg/l
NOEC Chronic Fish	0.168 mg/l QSAR (Reliability: 2)
Benzyl alcohol (100-51-6)	
LC50 Fish 1	460 mg/l (Exposure time: 96 h - Species: Pimephales promelas [static])
EC50 Daphnia 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])
ErC50 (Algae)	770 mg/l

12.2. Persistence and Degradability

Estradiol Valerate Injection, USP 20 mg/mL, 40mg/mL	
Persistence and Degradability	May cause long-term adverse effects in the environment.

12.3. Bioaccumulative Potential

Estradiol Valerate Injection, USP 20 mg/mL, 40mg/mL	
Bioaccumulative Potential	Not established.

Benzyl benzoate (120-51-4)	
Log Pow	3.97

Benzyl alcohol (100-51-6)	
Log Pow	1.1

12.4. Mobility in Soil

Estradiol Valerate Injection, USP 20 mg/mL, 40mg/mL	
Ecology - Soil	Not established.

12.5. Other Adverse Effects

Other Information : Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste Treatment Methods

Waste Disposal Recommendations: Dispose of contents/container in accordance with local, regional, national, and international regulations.

Additional Information: Container may remain hazardous when empty. Continue to observe all precautions.

Ecology - Waste Materials: Avoid release to the environment. This material is hazardous to the aquatic environment. Keep out of sewers and waterways.

SECTION 14: TRANSPORT INFORMATION

The shipping description(s) stated herein were prepared in accordance with certain assumptions at the time the SDS was authored, and can vary based on a number of variables that may or may not have been known at the time the SDS was issued.

14.1. In Accordance with DOT

Proper Shipping Name : ENVIRONMENTALLY HAZARDOUS SUBSTANCES, LIQUID, N.O.S. (Benzyl benzoate mixture)
Hazard Class : 9
Identification Number : UN3082
Label Codes : 9
Packing Group : III
Marine Pollutant : Marine pollutant
ERG Number : 171



14.2. In Accordance with IMDG

Proper Shipping Name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Benzyl benzoate mixture)
Hazard Class : 9
Identification Number : UN3082
Packing Group : III
Label Codes : 9
EmS-No. (Fire) : F-A
EmS-No. (Spillage) : S-F
Marine Pollutant : Marine pollutant



14.3. In Accordance with IATA

Proper Shipping Name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Benzyl benzoate mixture)
Packing Group : III

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Identification Number : UN3082
Hazard Class : 9
Label Codes : 9
ERG Code (IATA) : 9L



SECTION 15: REGULATORY INFORMATION

15.1. US Federal Regulations

Estradiol Valerate Injection, USP 20 mg/mL, 40mg/mL	
SARA Section 311/312 Hazard Classes	Health hazard - Carcinogenicity Health hazard - Reproductive toxicity Health hazard - Acute toxicity (any route of exposure)
Benzyl benzoate (120-51-4)	
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	
Castor oil (8001-79-4)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	

15.2. US State Regulations

Benzyl alcohol (100-51-6)
U.S. - Massachusetts - Right To Know List U.S. - Pennsylvania - RTK (Right to Know) List

SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

Date of Preparation or Latest Revision : 05/26/2020
Other Information : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200

GHS Full Text Phrases:

Acute Tox. 4 (Inhalation:dust,mist)	Acute toxicity (inhalation:dust,mist) Category 4
Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
Aquatic Acute 1	Hazardous to the aquatic environment - Acute Hazard Category 1
Aquatic Acute 2	Hazardous to the aquatic environment - Acute Hazard Category 2
Aquatic Chronic 2	Hazardous to the aquatic environment - Chronic Hazard Category 2
Carc. 1A	Carcinogenicity Category 1A
Eye Irrit. 2A	Serious eye damage/eye irritation Category 2A
Flam. Liq. 4	Flammable liquids Category 4
Repr. 1B	Reproductive toxicity Category 1B
H227	Combustible liquid
H302	Harmful if swallowed
H319	Causes serious eye irritation
H332	Harmful if inhaled
H350	May cause cancer
H360	May damage fertility or the unborn child
H400	Very toxic to aquatic life
H401	Toxic to aquatic life
H411	Toxic to aquatic life with long lasting effects

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.

SDS US (GHS HazCom)