



# Elestrin (estradiol gel) 0.06% gel (Metered-dose pump)

## SAFETY DATA SHEET

North America GHS

According to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations & the Hazardous Products Regulation (February 11, 2015) & NORMA Oficial Mexicana NOM-018-STPS-2015

### 1. IDENTIFICATION

#### Product identifier

**Product Name:** Elestrin (estradiol gel) 0.06% gel (Metered-dose pump)

**Synonyms:** Estradiol Gel, 0.06%; Elestrin<sup>®</sup> (0.52 mg estradiol delivered per actuation)

#### Other means of identification

**Other Information:** No other information

#### Recommended use of the chemical and restrictions on use

**Recommended Use:** For external use only. Pharmaceutical. Use only as directed.

The intent of this safety data sheet (SDS) is to provide safety information for occupational handling of this product. This information may not be relevant for medical use of this product. Patients/ consumers should consult the package insert/ product label/ physician/ pharmacist for information regarding the usage of this product. For information on the ingredients used in this product, refer to the appropriate SDS for each ingredient.

**Uses advised against:** No information available.

#### Details of the supplier of the safety data sheet

Mylan Inc.

Robert J. Coury Global Center

1000 Mylan Blvd.

Canonsburg, PA 15317, USA

+1.724.514.1800

**Contact e-mail:**

[SDScontact@mylan.com](mailto:SDScontact@mylan.com)

For any suspected reports of adverse events, product quality complaints or medical/product information questions, please email: [druginfo@mylan.com](mailto:druginfo@mylan.com).

#### Emergency telephone number

**Emergency Telephone:**

24 hr. Emergency Contact ChemTel

**International:** +1-813-248-0585

**US & Canada:** 1-800-255-3924

**Mexico:** 800-099-0731

#### Other Contact Information

**FDA Adverse Events Reporting Number:**

For reporting adverse health events call:  
+1 877-446-3679

### 2. HAZARDS IDENTIFICATION

**Pharmaceutical Agent – Handling of this product in its final form presents minimal occupational exposure risk**

**Patients/Consumers:** Please refer to the product information insert or product label for appropriate consumer-specific information about this product when used according to the physician's directions

#### Classification

Serious eye damage/eye irritation, Category 2A

Flammable liquids Category 2

#### Label elements



<b>Signal word:</b>	Danger
<b>Hazard statements:</b>	H319 - Causes serious eye irritation H225 - Highly flammable liquid and vapor
<b>Precautionary Statements - Prevention:</b>	Wash face, hands and any exposed skin thoroughly after handling Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking Keep container tightly closed Ground/bond container and receiving equipment Use only non-sparking tools Take precautionary measures against static discharge Wear protective gloves/eye protection/face protection Use explosion-proof electrical/ ventilating/ lighting/ equipment
<b>Precautionary Statements - Response:</b>	
<b>Eyes:</b>	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing If eye irritation persists: Get medical advice/attention
<b>Skin:</b>	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower
<b>Fire:</b>	In case of fire: Use CO2, dry chemical, or foam to extinguish
<b>Precautionary Statements - Storage:</b>	Store in a well-ventilated place. Keep cool
<b>Precautionary Statements - Disposal:</b>	Dispose of contents/container to an approved waste disposal plant
<b>Other Hazards</b>	
	No information available.
<b>Unknown acute toxicity</b>	
	No information available

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

#### Mixture

Chemical name	CAS No	Weight-%	Hazard statements
Ethanol	64-17-5	40 - 60	H225 - Highly flammable liquid and vapor H319 - Causes serious eye irritation
Estradiol	50-28-2	0.06	H350 - May cause cancer H360 - May damage fertility or the unborn child H400 - Very toxic to aquatic life H410 - Very toxic to aquatic life with long lasting effects

### 4. FIRST AID MEASURES

This is a pharmaceutical product in its final form. The risk of harmful exposure in the workplace is limited; however, the following guidance may be used as needed.

#### Description of first aid measures

**Overdose:** Refer to information on package labeling and packaging. In case of overdose, get medical help or contact a Poison Control Center right away.

**General advice:** Show this safety data sheet to the doctor in attendance.

**Inhalation:** Remove to fresh air.

**Skin contact:** Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes.

**Eye contact:** Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Keep eye wide open while rinsing. Do not rub affected area. Get medical attention if irritation develops and persists.

**Ingestion:** Clean mouth with water and drink afterwards plenty of water. Never give anything by mouth to an unconscious person. Do NOT induce vomiting. Call a physician.

**Self-protection of the first aider:** Remove all sources of ignition. Ensure that medical personnel are aware of the material(s) involved, take precautions to protect themselves and prevent spread of contamination. Use personal protective equipment as required. See section 8 for more information. Avoid contact with skin, eyes or clothing.

#### Most important symptoms and effects, both acute and delayed

**Symptoms:** Breast pain. Menstrual irregularities. Nausea. Vomiting. May cause eye irritation.

#### Indication of any immediate medical attention and special treatment needed

Treat symptomatically. In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

### 5. FIRE-FIGHTING MEASURES

#### Extinguishing media

**Suitable Extinguishing Media:** Dry chemical. Carbon dioxide (CO2). Water spray. Alcohol resistant foam.

**Unsuitable extinguishing media:** CAUTION: Use of water spray when fighting fire may be inefficient.

**Specific hazards arising from the chemical****Fire hazard:** Flammable.**Explosive hazard:** Not an explosive.**Reactivity:** Hazardous reactions will not occur under normal conditions.**Hazardous combustion products:** Carbon oxides.**Advice for firefighters****Precautionary measures in case of fire:** Standard procedure for chemical fires.**Firefighting instructions:** Use water spray or fog; do not use straight streams.**Protection of Firefighters:** Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear.**Other Information:** Refer to Section 9 for flammability properties.**Sensitivity to Static Discharge** Yes.**6. ACCIDENTAL RELEASE MEASURES**

This is a pharmaceutical product in its final form. The risk of harmful exposure in the workplace is limited; however, the following guidance may be used as needed.

**Personal precautions, protective equipment and emergency procedures****Personal precautions:** Evacuate personnel to safe areas. See section 8 for more information. Ensure adequate ventilation. Keep people away from and upwind of spill/leak. ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Pay attention to flashback. Take precautionary measures against static discharges. All equipment used when handling the product must be grounded. Do not touch or walk through spilled material. Avoid contact with skin, eyes or clothing. Use personal protective equipment as required.**For non-emergency personnel****Personal Protective Equipment:** Use personal protective equipment as required.**Emergency procedures:** Evacuate personnel to safe areas.**For emergency responders****Personal Protective Equipment:** Use personal protective equipment as required.**Emergency procedures:** Evacuate personnel to safe areas. Ventilate the area. Eliminate all ignition sources if safe to do so.**Other Information:** Ventilate the area. Refer to protective measures listed in Sections 7 and 8.**Environmental precautions**

Refer to protective measures listed in Sections 7 and 8. Prevent further leakage or spillage if safe to do so. Prevent product from entering drains.

**Methods and material for containment and cleaning up****Methods for containment:** Stop leak if you can do it without risk. Do not touch or walk through spilled material. A vapor suppressing foam may be used to reduce vapors. Dike far ahead of spill to collect runoff water. Keep out of drains, sewers, ditches and waterways. Absorb with earth, sand or other non-combustible material and transfer to containers for later disposal.**Methods for cleaning up:** Take precautionary measures against static discharges. Dam up. Soak up with inert absorbent material. Pick up and transfer to properly labeled containers.**Prevention of secondary hazards:** Clean contaminated objects and areas thoroughly observing environmental regulations.**Reference to other sections**

See section 8 for more information. See section 13 for more information.

**7. HANDLING AND STORAGE****Precautions for safe handling****Patients/Consumers:** Patients should adhere to the instructions provided within the product information insert or product label for appropriate consumer-specific information about this product when used according to the physician's directions.**Advice on safe handling:** Use personal protection equipment. Avoid breathing vapors or mists. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Use with local exhaust ventilation. Use according to package label instructions. Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product.**Conditions for safe storage, including any incompatibilities****Storage Conditions:** Keep at temperatures between 20 and 25 °C (68 and 77 °F). Keep containers tightly closed in a dry, cool and well-ventilated place. Keep in properly labeled containers. Do not store near combustible materials. Store in accordance with the particular national regulations. Store in accordance with local regulations.**Specific end use(s):** Pharmaceutical. Use only as directed. Refer to product insert for usage instructions and product information.**8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

This is a pharmaceutical product in its final form. The risk of harmful exposure in the workplace is limited; however, the following guidance may be used as needed.

**Control parameters****Exposure Limits:** No information available**Exposure controls****Appropriate engineering controls:** Site-specific risk assessments should be conducted to determine the appropriate exposure control

measures. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits.

#### **Individual protection measures, such as personal protective equipment**

**Hand protection:** Impervious gloves. Wear suitable gloves.

**Eye/face protection:** If splashes are likely to occur: Wear safety glasses with side shields (or goggles).

**Skin and body protection:** Long sleeved clothing. Chemical resistant apron. Antistatic boots. Wear suitable protective clothing.

**Respiratory protection:** Use appropriate respiratory protection.

**General hygiene considerations:** Contaminated work clothing should not be allowed out of the workplace. Regular cleaning of equipment, work area and clothing is recommended. Wash hands before breaks and immediately after handling the product. Avoid contact with skin, eyes or clothing. Wear suitable gloves and eye/face protection. Do not eat, drink or smoke when using this product.

## **9. PHYSICAL AND CHEMICAL PROPERTIES**

### **Information on basic physical and chemical properties**

<b>Physical state:</b>	Liquid
<b>Appearance:</b>	Gel
<b>Color:</b>	colorless
<b>Odor:</b>	No data available
<b>Odor threshold:</b>	No data available
<b>pH:</b>	No data available
<b>Melting point / freezing point:</b>	No data available
<b>Boiling point / boiling range:</b>	No data available
<b>Flash point:</b>	No data available
<b>Evaporation rate:</b>	No data available
<b>Flammability (solid, gas):</b>	No data available
<b>Upper flammability limit:</b>	No data available
<b>Lower flammability limit:</b>	No data available
<b>Vapor pressure:</b>	No data available
<b>Vapor density:</b>	No data available
<b>Relative density:</b>	No data available
<b>Water solubility:</b>	No data available
<b>Solubility in other solvents:</b>	No data available
<b>Partition coefficient:</b>	No data available
<b>Autoignition temperature:</b>	No data available
<b>Decomposition temperature:</b>	No data available
<b>Kinematic viscosity:</b>	No data available
<b>Dynamic viscosity:</b>	No data available
<b>Explosive properties:</b>	No data available
<b>Oxidizing properties:</b>	No data available
<b><u>Other Information</u></b>	
<b>VOC Content (%):</b>	No data available

## **10. STABILITY AND REACTIVITY**

### **Reactivity**

Hazardous reactions will not occur under normal conditions.

### **Chemical stability**

Stable under normal conditions.

### **Possibility of hazardous reactions**

None under normal processing.

### **Conditions to avoid**

Heat, flames and sparks.

### **Incompatible materials**

Strong oxidizing agents, strong acids, and strong bases.

### **Hazardous decomposition products**

Decomposition will not occur under normal conditions.

## **11. TOXICOLOGICAL INFORMATION**

### **Information on toxicological effects**

#### **Information on likely routes of exposure**

**Inhalation:** May cause irritation of respiratory tract.

**Ingestion:** Not an expected route of exposure.

**Eye contact:** Causes serious eye irritation. May cause redness, itching, and pain.

**Skin contact:** May cause irritation or rash.

**Symptoms related to the physical, chemical and toxicological characteristics**

**Symptoms:** Breast pain. Menstrual irregularities. Nausea. Vomiting. May cause eye irritation.

**Delayed and immediate effects as well as chronic effects from short and long-term exposure**

**Skin corrosion/irritation:** May cause skin irritation.

**Serious eye damage/eye irritation:** Irritating to eyes.

**Respiratory or skin sensitization:** Based on available data, the classification criteria are not met.

**Germ cell mutagenicity:** Based on available data, the classification criteria are not met.

**Carcinogenicity:** Contains a known or suspected carcinogen.

**Reproductive toxicity:** Contains material that may cause adverse reproductive effects.

**STOT - single exposure:** Based on available data, the classification criteria are not met.

**STOT - repeated exposure:** Based on available data, the classification criteria are not met.

**Aspiration hazard:** Based on available data, the classification criteria are not met.

**Numerical measures of toxicity**

**Acute toxicity:** No information available

## 12. ECOLOGICAL INFORMATION

**Ecotoxicity**

No information available.

**Persistence and degradability**

No information available.

**Bioaccumulation**

No information available.

**Mobility**

No information available.

**Other adverse effects**

No information available.

## 13. DISPOSAL CONSIDERATIONS

**Waste treatment methods**

Should not be released into the environment. Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.

**Contaminated packaging:** Empty containers pose a potential fire and explosion hazard. Do not cut, puncture or weld containers.

**California Hazardous Waste Status**

This product contains one or more substances that are listed with the State of California as a hazardous waste.

Chemical name	Weight-%	California Hazardous Waste Status
Ethanol (CAS #: 64-17-5)	40 - 60	Toxic Ignitable

## 14. TRANSPORT INFORMATION

Transportation requirements can vary based on numerous factors such as regional regulations and shipment volume. It is the responsibility of the transporting organization to ensure compliance with all applicable laws and regulations regarding the transportation of this product.

**DOT**

<b>UN/ID no</b>	UN 1170
<b>Proper shipping name</b>	Ethanol solution
<b>Hazard Class</b>	3
<b>Packing Group</b>	II



**Special Provisions** DOT - 24; DOT - IB2; DOT - T4; DOT - TP1

**TDG**

<b>UN/ID no</b>	UN 1170
<b>Proper shipping name</b>	ETHYL ALCOHOL SOLUTION
<b>Hazard Class</b>	3
<b>Packing Group</b>	II



**Special Provisions**

TDG - 150

**IATA**

**UN/ID no**  
**Proper shipping name**  
**Hazard Class**  
**Packing Group**

UN 1170  
 Ethanol solution  
 3  
 II



**Special Provisions**

IATA - A3; IATA - A58; IATA - A180

**IMDG**

**UN/ID no**  
**Proper shipping name**  
**Hazard Class**  
**Packing Group**

UN 1170  
 ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)  
 3  
 II



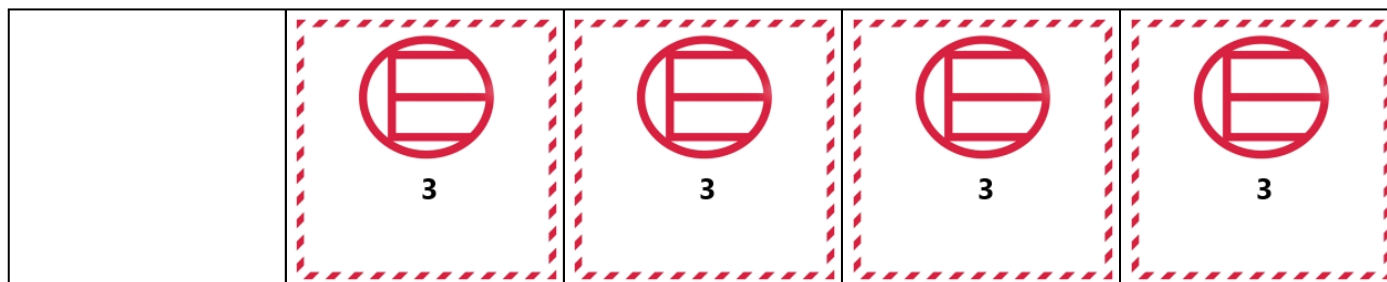
**Special Provisions**

IMDG - 144

	DOT	TDG	IATA	IMDG
<b>Limited Quantity **</b>	10 L	1 L	1 L	1 L

\*\*Limited quantities provide the maximum quantity per inner packaging or article for carrying dangerous goods as limited quantities in accordance with the regulations.

	DOT	TDG	IATA	IMDG
<b>Excepted Quantity - Inner Packaging #</b>	30 mL	30 mL	30 mL	30 mL
<b>Excepted Quantity - Outer Packaging #</b>	500 mL	500 mL	500 mL	500 mL



# Dangerous goods regulations may not be applicable to a shipment that satisfies the quantity limits and other excepted quantity regulations.

## 15. REGULATORY INFORMATION

### Safety, health and environmental regulations/legislation specific for the substance or mixture

#### International Regulations

**Ozone-depleting substances (ODS):** Not applicable

**Persistent Organic Pollutants:** Not applicable

**The Rotterdam Convention:** Not applicable

#### US Federal Regulations

**SARA 313:** Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

#### CWA (Clean Water Act)

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

#### CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

#### U.S. State Right-to-Know Regulations

##### US State Regulations:

Chemical name	New Jersey	Massachusetts	Pennsylvania
Ethanol 64-17-5	X	X	X
Propylene Glycol 57-55-6	X	-	X
Diethylene glycol monoethyl ether 111-90-0	X	-	X
Triethanolamine 102-71-6	X	X	X
Estradiol 50-28-2	-	X	X

#### Canada

This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations (CPR) and the SDS contains all the information required by the CPR.

## 16. OTHER INFORMATION

#### Revision Date:

01-February-2021

#### Other Information:

This document has been prepared in accordance with standards for workplace safety. The precautionary statements and warning included might not apply in all cases. Your needs may vary depending on the potential for exposure in your workplace.

#### Key or legend to abbreviations and acronyms used in the safety data sheet:

##### Legend, Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

TWA: TWA (time-weighted average)

STEL: STEL (Short Term Exposure Limit)

#### Party responsible for the preparation of this document:

Mylan Global Environmental, Health, and Safety Department - Occupational Toxicology

Phone number: +1 304-559-2595

*This SDS has been prepared for occupational exposure and intended to address some end-user concerns; however, patients/consumers are also strongly encouraged to review the product information insert or product label for consumer-specific information about this product.*

*Patients/Consumers: Refer to the package insert or product label for appropriate consumer-specific information about this product when used according to manufacturer's directions. 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 completeness of the information 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.*

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