

## SECTION 1: IDENTIFICATION

### 1.1. Product Identifier

**Product Form:** Mixture

**Product Name:** Droperidol Injection, USP

**Product Code:** 2.5 mg/mL: 0517-9702-25

### 1.2. Intended Use of the Product

**Use of the Substance/Mixture:** Indicated to reduce the incidence of nausea and vomiting associated with surgical and diagnostic procedures. This product is a sterile, non-pyrogenic, aqueous solution for Intravenous or Intramuscular use only.

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

#### Company

Luitpold Pharmaceuticals, Inc.

P.O. Box 9001

Shirley, NY 11967

1-800-645-1706

[www.luitpold.com](http://www.luitpold.com)

### 1.4. Emergency Telephone Number

**Emergency Number** : CHEMTREC 1-800-424-9300

## SECTION 2: HAZARDS IDENTIFICATION

### 2.1. Classification of the Substance or Mixture

#### GHS-US Classification

Not classified

### 2.2. Label Elements

#### GHS-US Labeling

No labeling applicable

### 2.3. Other Hazards

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	Product Identifier	%	GHS-US classification
Water	(CAS-No.) 7732-18-5	99.7	Not classified
Droperidol	(CAS-No.) 548-73-2	0.3	Acute Tox. 4 (Oral), H302 Comb. Dust
L-Lactic acid	(CAS-No.) 79-33-4	Used for pH adjustment	Skin Irrit. 2, H315 Eye Dam. 1, H318 Aquatic Acute 3, H402
Sodium hydroxide	(CAS-No.) 1310-73-2	Used for pH adjustment	Met. Corr. 1, H290 Acute Tox. 3 (Oral), H301 Skin Corr. 1A, H314 Eye Dam. 1, H318 Aquatic Acute 3, H402

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 at least 15 minutes. Obtain medical attention if irritation develops or persists.

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**First-aid Measures After Eye Contact:** Rinse cautiously with water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention.

**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:** Not expected to present a significant hazard under anticipated conditions of normal use.

**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:** Ingestion may cause adverse effects.

**Symptoms/Injuries Upon Accidental Exposure Through Injection:** Exposure to this product may result in syncope, chills, shivering, dizziness, dysphoria, drowsiness and palpitations. Hypotension, arrhythmia and ventricular tachycardia may be observed following exposure. Hypersensitivity to this product is possible. See prescribing information.

**Chronic Symptoms:** None expected under normal conditions of use.

### 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, dry chemical, foam, carbon dioxide.

**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 flammable.

**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.

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

**Hazardous Combustion Products:** Carbon oxides (CO, CO<sub>2</sub>). Halogenated Compounds. Nitrogen oxides.

## SECTION 6: ACCIDENTAL RELEASE MEASURES

### 6.1. Personal Precautions, Protective Equipment and Emergency Procedures

**General Measures:** Avoid prolonged contact with eyes, skin and clothing. Avoid breathing (vapor, mist, spray).

#### 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.

### 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. 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

**Precautions for Safe Handling:** Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Avoid prolonged contact with eyes, skin and clothing. Avoid breathing vapors, mist, spray.

**Hygiene Measures:** Handle in accordance with good industrial hygiene and safety procedures.

### 7.2. Conditions for Safe Storage, Including Any Incompatibilities

**Technical Measures:** Comply with applicable regulations.

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**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.

**Incompatible Materials:** Water reactive materials.

### 7.3. Specific End Use(s)

Indicated to reduce the incidence of nausea and vomiting associated with surgical and diagnostic procedures. This product is a sterile, non-pyrogenic, aqueous solution for Intravenous or Intramuscular use 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).

Sodium hydroxide (1310-73-2)		
USA ACGIH	ACGIH Ceiling (mg/m <sup>3</sup> )	2 mg/m <sup>3</sup>
USA NIOSH	NIOSH REL (ceiling) (mg/m <sup>3</sup> )	2 mg/m <sup>3</sup>
USA IDLH	US IDLH (mg/m <sup>3</sup> )	10 mg/m <sup>3</sup>
USA OSHA	OSHA PEL (TWA) (mg/m <sup>3</sup> )	2 mg/m <sup>3</sup>

### 8.2. Exposure Controls

#### Appropriate Engineering Controls

: Emergency eye wash fountains and safety showers should be available in the immediate 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.



#### 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, colorless to slightly pale yellow
Odor	: Odorless
Odor Threshold	: No data available
pH	: 3 - 3.8
Evaporation Rate	: No data available
Melting Point	: No data available
Freezing Point	: 32 °F (0 °C)
Boiling Point	: 212 °F (100 °C)
Flash Point	: Not flammable
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
Specific Gravity	: ≈ 1
Solubility	: Water: Freely soluble
Partition Coefficient: N-Octanol/Water	: No data available

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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:** Water reactive materials.
- 10.6. **Hazardous Decomposition Products:** None expected under normal conditions of use.

## SECTION 11: TOXICOLOGICAL INFORMATION

### 11.1. Information on Toxicological Effects

Acute Toxicity: Not classified

<b>Droperidol (548-73-2)</b>	
LD50 Oral Rat	750 mg/kg
<b>L-Lactic acid (79-33-4)</b>	
LD50 Oral Rat	3730 mg/kg
LD50 Dermal Rabbit	> 2000 mg/kg
<b>Sodium hydroxide (1310-73-2)</b>	
LD50 Oral Rat	140 - 340 mg/kg

Skin Corrosion/Irritation: Not classified

pH: 3 - 3.8

Serious Eye Damage/Irritation: Not classified

pH: 3 - 3.8

Respiratory or Skin Sensitization: Not classified

Germ Cell Mutagenicity: Not classified

Carcinogenicity: Not classified

Reproductive Toxicity: Not classified

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: Ingestion may cause adverse effects.

Symptoms/Injuries Upon Accidental Exposure Through Injection: Exposure to this product may result in syncope, chills, shivering, dizziness, dysphoria, drowsiness and palpitations. Hypotension, arrhythmia and ventricular tachycardia may be observed following exposure. Hypersensitivity to this product is possible. See prescribing information.

Chronic Symptoms: None expected under normal conditions of use.

## SECTION 12: ECOLOGICAL INFORMATION

### 12.1. Toxicity

Ecology - General : Not classified.

<b>L-Lactic acid (79-33-4)</b>	
LC50 Fish 1	320 mg/l (Exposure time: 96 h - Species: Brachydanio rerio [semi-static])
EC50 Daphnia 1	240 mg/l (Exposure time: 48 h - Species: Daphnia magna)
LC50 Fish 2	100 - 180 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static])
EC50 Daphnia 2	180 - 320 mg/l (Exposure time: 48 h - Species: Daphnia magna [Static])
<b>Sodium hydroxide (1310-73-2)</b>	
LC50 Fish 1	45.4 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])
EC50 Daphnia 1	40 mg/l

### 12.2. Persistence and Degradability

<b>Droperidol Injection, USP</b>	
Persistence and Degradability	Not established.

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## 12.3. Bioaccumulative Potential

Droperidol Injection, USP	
Bioaccumulative Potential	Not established.
L-Lactic acid (79-33-4)	
Log Pow	-0.62

12.4. Mobility in Soil No additional information available

## 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.

**Ecology - Waste Materials:** Avoid release to the environment.

## 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 Not regulated for transport

14.2. In Accordance with IMDG Not regulated for transport

14.3. In Accordance with IATA Not regulated for transport

## SECTION 15: REGULATORY INFORMATION

### 15.1. US Federal Regulations

L-Lactic acid (79-33-4)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
Sodium hydroxide (1310-73-2)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
CERCLA RQ	1000 lb
Water (7732-18-5)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	

### 15.2. US State Regulations

Sodium hydroxide (1310-73-2)
U.S. - Massachusetts - Right To Know List
U.S. - New Jersey - Right to Know Hazardous Substance List
U.S. - Pennsylvania - RTK (Right to Know) - Environmental Hazard 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 : 04/11/2018

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. 3 (Oral)	Acute toxicity (oral) Category 3
Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
Aquatic Acute 3	Hazardous to the aquatic environment - Acute Hazard Category 3
Comb. Dust	Combustible Dust
Eye Dam. 1	Serious eye damage/eye irritation Category 1
Met. Corr. 1	Corrosive to metals Category 1
Skin Corr. 1A	Skin corrosion/irritation Category 1A
Skin Irrit. 2	Skin corrosion/irritation Category 2
H290	May be corrosive to metals
H301	Toxic if swallowed
H302	Harmful if swallowed

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H314	Causes severe skin burns and eye damage
H315	Causes skin irritation
H318	Causes serious eye damage
H402	Harmful to aquatic life

Refer to Luitpold/American Regent prescribing information for further information at:  
<http://www.americanregent.com/AllProducts.aspx>

*The information above is believed to be accurate and represents the best information currently available to American Regent. The information has not been verified and we cannot, therefore, guarantee its accuracy or completeness or adequacy for all persons and situations or as to the results to be obtained by use of the information. It is the user's obligation to evaluate and use this product safely and to comply with all applicable laws and regulations. WE MAKE NO WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR USE OR ANY OTHER WARRANTY, EXPRESSED OR IMPLIED, WITH RESPECT TO SUCH INFORMATION AND WE ASSUME NO LIABILITY RESULTING FROM ITS USE. Users should make their own investigations to determine the suitability of the information for their own particular purposes. The user assumes all risks from use of the product. In no event shall Luitpold, its subsidiaries, its affiliates and its contractors be liable for any claims, losses or damages of any third party, or for lost profits, or for any special, indirect, incidental, consequential or exemplary damages however arising, even if Luitpold has been advised of the possibility of such damages.*

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