

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Form: Solution

Product Name: Papaverine Hydrochloride Injection, USP

Product Code: 0517-4002-25; 0517-4010-01

1.2. Intended Use of the Product

Use of the substance/mixture: Recommended in various conditions accompanied by spasm of smooth muscle, such as vascular spasm associated with acute myocardial infarction (coronary occlusion), angina pectoris, peripheral and pulmonary embolism, peripheral vascular disease in which there is a vasospastic element, or certain cerebral angiospastic states; and visceral spasm, as in ureteral, biliary, or gastrointestinal colic.

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

Company

Luitpold Pharmaceuticals, Inc.

One Luitpold Drive

P.O. Box 9001

Shirley, NY 11967

1-800-645-1706

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

Classification (GHS-US)

Not classified

2.2. Label Elements

GHS-US Labeling

No labeling applicable

2.3. Other Hazards Exposure to this product may result in excessive sedation, central nervous system depression, headache, malaise, skin rash, vomiting, weakness, anorexia, constipation or diarrhea. Increases in heart rate, blood pressure and depth of respiration may be noted. Refer to package insert for more information.

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	%	Classification (GHS-US)
Water for injection	(CAS No) 7732-18-5	96.5 - 97	Not classified
Papaverine Hydrochloride	(CAS No) 61-25-6	3	Acute Tox. 4 (Oral), H302
Chlorobutanol	(CAS No) 57-15-8	≤ 0.5	Acute Tox. 4 (Oral), H302
Edetate disodium (EDTA)	(CAS No) 6381-92-6	0.01	Acute Tox. 4 (Oral), H302 Acute Tox. 4 (Dermal), H312 Acute Tox. 4 (Inhalation:dust,mist), H332 Skin Irrit. 2, H315 Eye Irrit. 2A, H319 STOT SE 3, H335 Aquatic Chronic 3, H412
Sodium citrate, dihydrate	(CAS No) 6132-04-3	Used to adjust pH	Comb. Dust
Citric acid	(CAS No) 77-92-9	Used to adjust pH	Comb. Dust Eye Irrit. 2A, H319

Full text of H-phrases: see section 16

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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 attention. (show the label where possible). In the event of accidental injection, immediately call a poison center and seek medical attention.

First-aid Measures After Inhalation: Go into open air and ventilate suspected area. Seek medical attention.

First-aid Measures After Skin Contact: Remove contaminated clothing. Flush with copious quantities of water for 15 minutes. Seek medical advice.

First-aid Measures After Eye Contact: Immediately flush eyes thoroughly with water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Seek medical attention.

First-aid Measures After Ingestion: Rinse mouth. Do NOT induce vomiting. Seek 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. Please refer to the package insert for more detailed information.

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

If you feel unwell, seek medical advice (show the label where possible).

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing Media

Suitable Extinguishing Media: Water spray, dry chemical, foam, carbon dioxide.

Unsuitable Extinguishing Media: A heavy water stream may spread burning liquid. CAUTION: Carbon dioxide is an asphyxiant. Lack of oxygen can be fatal.

5.2. Special Hazards Arising From the Substance or Mixture

Reactivity: Hazardous reactions will not occur under normal conditions.

5.3. Advice for Firefighters

Firefighting Instructions: Exercise caution when fighting any chemical fire. Use water spray or fog for cooling exposed containers.

Protection During Firefighting: Firefighters must use full bunker gear including NIOSH-approved positive-pressure self-contained breathing apparatus to protect against potential hazardous combustion and decomposition products.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Avoid all unnecessary exposure. Do not breathe vapor or mist.

6.1.1. For Non-emergency Personnel

Protective Equipment: Use appropriate personal protection equipment (PPE). Refer to section 8.2.

Emergency Procedures: Evacuate unnecessary personnel.

6.1.2. For Emergency Responders

Protective Equipment: Equip cleanup crew with proper protection. For further information refer to section 8: "Exposure controls/personal protection".

Emergency Procedures: Ventilate area.

6.2. Environmental Precautions Prevent entry to sewers and public waters.

6.3. Methods and Material for Containment and Cleaning Up

Methods for Cleaning Up: Vacuum spillage with a vacuum cleaner having a high efficiency particulate (HEPA) filter, or absorb liquid with clay absorbent, absorbent pads or paper towels. Use plastic tools to scoop up, sweep or containerize spilled material. Use plastic drums to contain spilled materials. Wipe working surfaces to dryness, and then wash with soap and water.

6.4. Reference to Other Sections See heading 8, Exposure Controls and Personal Protection.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling

Hygiene Measures: Handle in accordance with good industrial hygiene and safety procedures. Wash hands and other exposed areas with mild soap and water before eating, drinking, or smoking and again when leaving work.

7.2. Conditions for Safe Storage, Including Any Incompatibilities

Technical Measures: Comply with applicable regulations.

Storage Conditions: : Store in a dry, well ventilated place at 20° -25°C (68°- 77°F) away from direct sunlight and incompatible materials.

Incompatible Products: Strong bases. Strong oxidizers.

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7.3. Specific End Use(s)

Pharmaceutical.

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), NIOSH (REL), or OSHA (PEL).

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. Safety glasses.



Hand Protection : Wear chemically resistant protective gloves.

Eye Protection : Chemical goggles or safety glasses.

Skin and Body Protection : Wear suitable protective clothing. Wash contaminated clothing before reuse.

Respiratory Protection : In case of inadequate ventilation wear 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 pale yellow
Odor	: May possess an alcohol odor
Odor Threshold	: No data available
pH	: 3.0 - 4.5
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
Specific Gravity	: ≈ 1.0
Solubility	: Soluble in water
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. High or low temperatures. Incompatible materials.

10.5. Incompatible Materials: Strong oxidizers. Strong bases.

10.6. Hazardous Decomposition Products: Thermal decomposition generates: Carbon oxides (CO, CO₂), Halogenated compounds, Nitrogen oxides.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information On Toxicological Effects

Acute Toxicity: Not classified

Water (7732-18-5)	
LD50 Oral Rat	> 90000 mg/kg

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Papaverine Hydrochloride (61-25-6)	
LD50 Oral Rat	360 mg/kg
Citric acid (77-92-9)	
LD50 Oral Rat	5400 mg/kg
LD50 Dermal Rat	> 2000 mg/kg
Disodium EDTA, dihydrate (6381-92-6)	
ATE (Oral)	500.00 mg/kg body weight
ATE (Dermal)	1,100.00 mg/kg body weight
ATE (Dust/Mist)	1.50 mg/l/4h
Chlorobutanol (57-15-8)	
LD50 Oral Rat	510 mg/kg

Skin Corrosion/Irritation: Not classified (pH: 3.0 - 4.5)

Serious Eye Damage/Irritation: Not classified (pH: 3.0 - 4.5)

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

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity Not classified

Citric acid (77-92-9)	
LC50 Fish 1	1516 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static])

12.2. Persistence and Degradability Not established

Citric acid (77-92-9)	
Persistence and Degradability	Readily biodegradable in water.

12.3. Bioaccumulative Potential Not established

Citric acid (77-92-9)	
Log Pow	-1.72 (at 20 °C)

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

Sewage Disposal Recommendations: Do not empty into drains; dispose of this material and its container in a safe way.

Waste Disposal Recommendations: Dispose of waste material in accordance with all local, regional, national, and international regulations.

SECTION 14: TRANSPORT INFORMATION

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

Water (7732-18-5)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
Papaverine Hydrochloride (61-25-6)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
Citric acid (77-92-9)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
Chlorobutanol (57-15-8)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	

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15.2 US State Regulations

Neither this product nor its chemical components appear on any US state lists.

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

Revision Date : 11/10/2015

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 (Dermal)	Acute toxicity (dermal) Category 4
Acute Tox. 4 (Inhalation:dust,mist)	Acute toxicity (inhalation:dust,mist) Category 4
Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
Aquatic Chronic 3	Hazardous to the aquatic environment - Chronic Hazard Category 3
Comb. Dust	Combustible Dust
Eye Irrit. 2A	Serious eye damage/eye irritation Category 2A
Skin Irrit. 2	Skin corrosion/irritation Category 2
STOT SE 3	Specific target organ toxicity (single exposure) Category 3
Comb. Dust	May form combustible dust concentrations in air
H302	Harmful if swallowed
H312	Harmful in contact with skin
H315	Causes skin irritation
H319	Causes serious eye irritation
H332	Harmful if inhaled
H335	May cause respiratory irritation
H412	Harmful to aquatic life with long lasting effects

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.

SDS US (GHS HazCom)