

### SECTION 1: IDENTIFICATION

#### 1.1. Product Identifier

**Product Form:** Solution

**Product Name:** Caffeine Citrate Injection, USP

**Product Code:** 0517-0020-10; 0517-0020-25

#### 1.2. Intended Use of the Product

**Use of the substance/mixture:** Caffeine Citrate Injection is indicated for the short-term treatment of apnea of prematurity in infants between 28 and < 33 weeks gestational age.

#### 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](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 those with pre-existing eye, skin, or respiratory conditions. Acute overexposure to this product may result in irritability, restlessness, palpitations, tachycardia, insomnia, alterations in serum glucose and digestive disturbances. See package insert for additional 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	%	GHS-US classification
Water for Injection	(CAS No) 7732-18-5	97.7	Not classified
Caffeine, anhydrous	(CAS No) 58-08-2	1	Comb. Dust Acute Tox. 3 (Oral), H301 Acute Tox. 4 (Inhalation:dust,mist), H332 Aquatic Acute 3, H402
Sodium citrate dihydrate	(CAS No) 6132-04-3	0.8	Comb. Dust
Citric acid monohydrate	(CAS No) 5949-29-1	0.5	Eye Irrit. 2A, H319

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). 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. Obtain medical attention if breathing difficulty.

**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:** None expected under normal conditions of use. Acute overexposure to this product may result in irritability, restlessness, palpitations, tachycardia, insomnia, alterations in serum glucose and digestive disturbances. See package insert for additional information.

**Symptoms/Injuries After Inhalation:** May cause respiratory irritation.

**Symptoms/Injuries After Skin Contact:** May cause skin irritation.

**Symptoms/Injuries After Eye Contact:** May cause eye irritation.

**Symptoms/Injuries After Ingestion:** Ingestion is likely to be harmful or have adverse effects.

**Chronic Symptoms:** None known.

## 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:** Use extinguishing media appropriate for surrounding fire.

**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.

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

## SECTION 6: ACCIDENTAL RELEASE MEASURES

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

**General Measures:** Avoid breathing vapor, mist, spray. Avoid all contact with skin, eyes, or clothing.

#### 6.1.1. For Non-emergency Personnel

**Protective Equipment:** Use appropriate personal protection equipment (PPE).

**Emergency Procedures:** Evacuate unnecessary personnel.

#### 6.1.2. For Emergency Responders

**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.

### 6.2. Environmental Precautions

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

### 6.3. Methods and Material 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. Any vacuum used for clean-up must be equipped with high-efficiency (HEPA) filter. Transfer spilled material to a suitable container for disposal. Contact competent authorities after a spill.

### 6.4. Reference to Other Sections

See Section 8, Exposure Controls and Personal Protection. See Section 13, Disposal Considerations.

## SECTION 7: HANDLING AND STORAGE

### 7.1. Precautions for Safe Handling

**Additional Hazards When Processed:** Use only as directed by the information identified in the package insert. Heating of product can release toxic or irritating fumes; ensure proper ventilation is employed, proper precautions are enforced, and applicable regulations are followed. Any proposed use of this product in elevated-temperature processes should be thoroughly evaluated to assure that safe operating conditions are established and maintained.

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

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**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.

**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. Strong acids.

## 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), AIHA (WEEL), NIOSH (REL), or OSHA (PEL).

### 8.2. Exposure Controls

**Appropriate Engineering Controls** : Not generally required. 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.

**Personal Protective Equipment** : Gloves. Protective goggles. Insufficient ventilation: wear respiratory protection.



**Hand Protection** : Wear chemically resistant protective gloves.

**Eye Protection** : Chemical safety goggles.

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

**Respiratory Protection** : In case of inadequate ventilation wear respiratory protection.

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1. Information on Basic Physical and Chemical Properties

<b>Physical State</b>	: Liquid
<b>Appearance</b>	: Clear, colorless solution
<b>Odor</b>	: Odorless
<b>Odor Threshold</b>	: No data available
<b>pH</b>	: 4.2 - 5.2
<b>Evaporation Rate</b>	: No data available
<b>Melting Point</b>	: No data available
<b>Freezing Point</b>	: No data available
<b>Boiling Point</b>	: No data available
<b>Flash Point</b>	: Non-flammable, non-combustible
<b>Auto-ignition Temperature</b>	: No data available
<b>Decomposition Temperature</b>	: No data available
<b>Flammability (solid, gas)</b>	: No data available
<b>Vapor Pressure</b>	: No data available
<b>Relative Vapor Density at 20 °C</b>	: No data available
<b>Relative Density</b>	: No data available
<b>Specific Gravity</b>	: Approx. 1.0
<b>Solubility</b>	: Aqueous solution
<b>Partition Coefficient: N-Octanol/Water</b>	: No data available
<b>Viscosity</b>	: No data available

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## 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:** Do not mix with other drugs. Avoid heat, light and humidity. Keep away from flames; thermally decomposes to form toxic vapors.
- 10.5. Incompatible Materials:** Strong bases. Strong oxidizers. Strong acids.
- 10.6. Hazardous Decomposition Products:** Thermal decomposition generates: Carbon oxides (CO, CO<sub>2</sub>). Nitrogen oxides. Toxic vapors.

## SECTION 11: TOXICOLOGICAL INFORMATION

### 11.1. Information on Toxicological Effects

**Acute Toxicity:** Not classified

Caffeine (58-08-2)	
LD50 Oral Rat	247 mg/kg (Species: Wistar)
LD50 Dermal Rat	> 2000 mg/kg
LC50 Inhalation Rat	4.94 mg/l/4h
LC50 Inhalation Rat	4.1 mg/l/4h
Citric acid monohydrate (5949-29-1)	
LD50 Oral Rat	5790 mg/kg

**Skin Corrosion/Irritation:** Not classified

**pH:** 4.2 - 5.2

**Serious Eye Damage/Irritation:** Not classified

**pH:** 4.2 - 5.2

**Respiratory or Skin Sensitization:** Not classified

**Germ Cell Mutagenicity:** Not classified

**Carcinogenicity:** Not classified

Caffeine (58-08-2)	
IARC group	3

**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:** May cause respiratory irritation.

**Symptoms/Injuries After Skin Contact:** May cause skin irritation.

**Symptoms/Injuries After Eye Contact:** May cause eye irritation.

**Symptoms/Injuries After Ingestion:** Ingestion is likely to be harmful or have adverse effects.

**Chronic Symptoms:** None known.

## SECTION 12: ECOLOGICAL INFORMATION

### 12.1. Toxicity

**Ecology - General** : Not classified.

Caffeine (58-08-2)	
LC50 Fish 1	151 mg/l (Exposure time: 96 h - Species: Pimephales promelas [flow-through])
EC50 Daphnia 1	182 mg/l (Exposure time: 48 h - Species: Daphnia magna)
LC 50 Fish 2	97 mg/l (Exposure time: 96 h - Species: Leuciscus idus)

### 12.2. Persistence and Degradability

Caffeine Citrate Injection, USP	
Persistence and Degradability	Not established.

### 12.3. Bioaccumulative Potential

Caffeine Citrate Injection, USP	
Bioaccumulative Potential	Not established.

### 12.4. Mobility in Soil No additional information available

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## 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 contents/container in accordance with local, regional, national, and international regulations.

**Additional Information:** Contaminated sharps should be handled with care and discarded immediately or as soon as possible in containers that are closable, puncture-resistant, leak proof on sides and bottoms, and appropriately labeled. Contact your local health department for referral to a syringe disposal program.

## 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

#### Caffeine (58-08-2)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

#### Water (7732-18-5)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

**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** : 11/23/2015

**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. 3 (Oral)	Acute toxicity (oral) Category 3
Acute Tox. 4 (Inhalation:dust,mist)	Acute toxicity (inhalation:dust,mist) Category 4
Aquatic Acute 3	Hazardous to the aquatic environment - Acute Hazard Category 3
Comb. Dust	Combustible Dust
Eye Irrit. 2A	Serious eye damage/eye irritation Category 2A
Comb. Dust	May form combustible dust concentrations in air
H301	Toxic if swallowed
H319	Causes serious eye irritation
H332	Harmful if inhaled
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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