

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Form: Solution

Product Name: Indigo Carmine Injection

Product Code: 0517-0375-05

1.2. Intended Use of the Product

Use of the substance/mixture: Originally employed as a kidney function test, the chief application of Indigo Carmine at present is localizing ureteral orifices during cystoscopy and ureteral catheterization.

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

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

No additional information available

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	99.2	Not classified
Indigotindisulfonate Sodium	(CAS No) 860-22-0	0.8	Acute Tox. 4 (Oral), H302
Sodium Citrate	(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

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 or seek medical advice.

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.

First-aid Measures After Eye Contact: Rinse cautiously with water for at least 15 minutes. Remove contact lenses, if present and easy to do so. Continue rinsing. Obtain medical attention if irritation 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: None expected under normal conditions of use.

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

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

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

Symptoms/Injuries After Ingestion: Ingestion may cause 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.

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: Product is 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 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.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Avoid all unnecessary exposure.

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

Avoid release to the environment.

6.3. Methods and Material for Containment and Cleaning Up

Methods for Cleaning Up: Clean up accidental release immediately and dispose of waste safely.

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.

Precautions for Safe Handling: Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work.

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: Keep container closed when not in use. Store in a dry, cool place. Keep/Store away from direct sunlight, high or low temperatures and incompatible materials.

Incompatible Products: Strong acids. Strong bases. Strong oxidizers.

Storage Temperature: 20 - 25 °C (68 - 77 °F)

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).

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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.



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.

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	: Dark blue solution
Odor	: Odorless
Odor Threshold	: No data available
pH	: 3.0 - 6.5
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)	: No data available
Vapor Pressure	: No data available
Relative Vapor Density at 20 °C	: No data available
Relative Density	: No data available
Specific Gravity	: ≈ 1
Solubility	: Aqueous Solution
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: 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 oxidizers.

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

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information On Toxicological Effects

Acute Toxicity: Not classified

Indigotindisulfonate Sodium (860-22-0)	
LD50 Oral Rat	2000 mg/kg
Citric acid (77-92-9)	
LD50 Oral Rat	5400 mg/kg
LD50 Dermal Rat	> 2000 mg/kg

Skin Corrosion/Irritation: Not classified (pH: 3.0 - 6.5)

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Serious Eye Damage/Irritation: Not classified (pH: 3.0 - 6.5)
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
Symptoms/Injuries After Inhalation: Prolonged exposure may cause irritation.
Symptoms/Injuries After Skin Contact: May cause skin irritation.
Symptoms/Injuries After Eye Contact: May cause eye irritation.
Symptoms/Injuries After Ingestion: Ingestion may cause adverse effects.
Chronic Symptoms: None known.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecology - General : Not classified.

Citric acid (77-92-9)

LC50 Fish 1	1516 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static])
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12.2. Persistence and Degradability

Citric acid (77-92-9)

Persistence and Degradability	Readily biodegradable in water.
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12.3. Bioaccumulative Potential

Citric acid (77-92-9)

Log Pow	-1.72 (at 20 °C)
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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

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

Indigotindisulfonate Sodium (860-22-0)

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

SARA Section 311/312 Hazard Classes	Immediate (acute) health hazard
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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 : 3/6/2017

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 (Oral)	Acute toxicity (oral) Category 4
Comb. Dust	Combustible Dust
Eye Irrit. 2A	Serious eye damage/eye irritation Category 2A

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H302	Harmful if swallowed
H319	Causes serious eye irritation

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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