

SECTION 1: IDENTIFICATION

1.1. Product identifier

Product form: Solution for injection

Product name: Bludigo, Indigotindisulfonate Sodium 0.8%

Product codes: NA

Molecular Formula: NA

CAS No.: NA

EC No.: NA

1.2. Intended Use of the Product

Use as a visualization aid in the delineation of the integrity and patency of the ureters and bladder during urological and gynecological open, robotic, or endoscopic surgical procedures.

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

Company	Supplier
Provepharm 22 rue Marc Donadille 13013 Marseille, France t: +33 (0)4 91 08 69 30 f: +33 (0)4 91 08 69 01 www.provepharm.com contact : hse@provepharm.com	Cenexi 52 rue Marcel et Jacques Gaucher - BP 41 94120 Fontenay sous-bois, France t: +33 (0)1 43 94 88 00 www.cenexi.com

1.4. Emergency telephone number: CHEMTREC 1-800-424-9300

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture: No classification applicable

2.2. Label elements: No labeling applicable

2.3. Other hazards: No data

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substance

Component	CAS No.	EC No.	Quantity/mL
Indigotindisulfonate Sodium	860-22-0	212-728-8	40.0mg
Water for injection	7732-18-5	231-791-2	q.s. 5.0mL
Citric acid monohydrate	5949-29-1	201-069-1	Solutions at 0.1N, if necessary, to reach pH at 3.0-6.5
Trisodium citrate dihydrate	6132-04-3	200-675-3	

SECTION 4: FIRST-AID MEASURES

4.1. Description of first-aid measures

First-aid measures general: Consult a doctor if you feel unwell. Provide fresh air and keep them in a position where they can comfortably breathe.

First-aid measures after inhalation: Move to fresh air. If not breathing, give artificial respiration. Do not use mouth-to-mouth method if victim ingested or inhaled the substance; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Obtain medical attention.

First-aid measures after skin contact: Remove soiled clothing. Wash with care and plenty of water and soap. If irritation or rash occurs: Get medical attention.

First-aid measures after eye contact: Remove contact lenses, if present and easy to do. Continue rinsing. Rinse cautiously with water for several minutes. Consult a physician if pain or redness persists.

First-aid measures after ingestion: Rinse the mouth. Do not induce vomiting. Provide fresh air and ventilate the suspect area. Consult a doctor urgently.

4.2. Most important symptoms and effects, both acute and delayed

Cumulative effects may result following exposure.

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

Treat symptomatically.

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing media

Suitable Extinguishing Media: Water spray. Sand. Carbon dioxide. Foam. Dry powder.

Unsuitable Extinguishing Media: None.

5.2. Special hazards arising from the substance or mixture

Reactivity: No information available.

5.3. Advice for firefighters

Firefighting Instructions: Suitable protective equipment recommended.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

General measures: Use of personal protective equipment recommended in Section 8 of this document and isolate the hazard area.

6.1.1. For non-emergency personnel

Emergency Procedures: Keep superfluous staff away. Mechanically ventilate the spill area.

6.1.2. For emergency responders

Protective equipment: Provide adequate protection to cleaning crews. Do not use without suitable protective equipment.

Emergency procedures: Air the area.

6.2. Environmental precautions

Avoid entering sewers and drinking water. Avoid release into the environment.

6.3. Methods and material for containment and cleaning up

Methods for containment: Collect the spilled product.

Methods for cleaning Up: Absorb spilled liquid in absorbent material. Absorb any spilled substance to prevent it from attacking surrounding materials.

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

Handling is performed in a well-ventilated place. Avoid contact with skin and eyes. Wash hands and other exposed areas with mild soap and water before eating, drinking, smoking, and before leaving work.

7.2. Conditions for safe storage, including any incompatibilities

Store in a closed container. Keep only in the original container in a dry, cool and well-ventilated place. Keep closed containers out of their use.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

This product does not contain any hazardous materials with occupational exposure limits established by the region-specific regulatory bodies.

8.2. Exposure controls

Appropriate engineering controls : Ensure good ventilation of the workstation. Avoid any unnecessary exposure

Personal protective equipment :



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.

Consumer exposure controls : Do not eat or drink

Other information : This safety data sheet corresponds to the specific conditions which justified the registration of the substance as an isolated intermediate. Do not eat, drink or smoke while using.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on Basic Physical and Chemical Properties

Appearance : Dark blue or bluish-purple solution

Odor : Solution odorless

Odor threshold : No information available

pH : 3.0 – 6.5

Relative evaporation rate : No data

Melting point : No data

Freezing point	: No data
Boiling point	: No data
Flash point	: > 300 °C
Auto-ignition temperature	: No data
Decomposition temperature	: No data
Flammability (solid, gas)	: No data
Vapor pressure	: No data
Relative vapor density at 20 °C	: No data
Relative density	: No data
Specific gravity	: No data
Solubility	: Aqueous solution
Viscosity	: No data

SECTION 10: STABILITY AND REACTIVITY

- 10.1 Reactivity:** No additional information available
- 10.2 Chemical stability:** Stable under recommended storage conditions
- 10.3 Possibility of hazardous reactions:** No additional information available
- 10.4 Conditions to avoid:** Direct rays of the sun. Extremely high or extremely low temperatures.
- 10.5 Incompatible materials:** Strong acids. Strong bases.
- 10.6 Hazardous decomposition products:** Fumes. Carbon monoxide. Carbon dioxide

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Acute toxicity

Component	CAS No.	LD ₅₀ (oral)	LD ₅₀ (dermal)	LD ₅₀ (inhalation)
Indigotindisulfonate Sodium	860-22-0	2000mg/kg (rat)	NA	NA
Citric acid monohydrate	5949-29-1	5400mg/kg (mouse)	> 2000mg/kg	NA
Trisodium citrate dihydrate	6132-04-3	8000mg/kg (rat)	NA	NA

11.2. Carcinogenicity

Component	CAS No.	IARC	NTP
Indigotindisulfonate Sodium	860-22-0	Not Listed	Not Listed
Citric acid monohydrate	5949-29-1	Not Listed	Not Listed
Trisodium citrate dihydrate	6132-04-3	Not Listed	Not Listed

11.3. Others

- Skin corrosion/irritation** : May cause irritation
- Serious eye damage/irritation** : No information available
- Respiratory or skin sensitization** : No information available

Reproductive toxicity : No information available
STOT-single exposure : No information available

SECTION 12: ECOLOGICAL INFORMATION

12.1. Ecotoxicity: No information available.

12.2. Persistence and Degradability

Component	CAS No.	Persistence (water/soil)	Persistence (air)
Indigotindisulfonate Sodium	860-22-0	High	High
Water for injection	7732-18-5	Low	Low
Citric acid monohydrate	5949-29-1	No	No
Trisodium citrate dihydrate	6132-04-3	Low	Low

12.3. Bioaccumulative Potential

Component	CAS No.	Bioaccumulative potential	Comments
Indigotindisulfonate Sodium	860-22-0	Low	Log Kow=-3.70
Water for injection	7732-18-5	Low	Log Kow=-1.38
Citric acid monohydrate	5949-29-1	No	NA
Trisodium citrate dihydrate	6132-04-3	No information available	No information available

12.4. Mobility in Soil

Component	CAS No.	Mobility in soil	Soil organic carbon-water partitioning coefficient (Koc)
Indigotindisulfonate Sodium	860-22-0	Low	99.07
Water for injection	7732-18-5	Low	14.1
Citric acid monohydrate	5949-29-1	No information available	No information available
Trisodium citrate dihydrate	6132-04-3	No information available	No information available

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste disposal recommendations: Chemical waste generators must determine whether a discarded chemical is classified as a hazardous waste. Chemical waste generators must also consult local, regional, and national hazardous waste regulations to



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Safety Data Sheet

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ensure complete and accurate classification.

SECTION 14: TRANSPORT INFORMATION

14.1 In Accordance with DOT: Not regulated

14.2 In Accordance with IMDG: Not regulated

14.3 In Accordance with IATA: Not regulated

14.4 In Accordance with TDG: Not regulated

SECTION 15: REGULATORY INFORMATION

15.1 International chemical inventories

Component	EINECS	TSCA	DSL	IECSC	NZIoC	PICCS	KECI	AICS	ENCS
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Legend:

EINECS	:	European Inventory of Existing Commercial Chemical Substances
TSCA	:	United States Toxic Substances Control Act Inventory
DSL	:	Canadian Domestic Substances List
IECSC	:	China Inventory of Existing Chemical Substances
NZIoC	:	New Zealand Inventory of Chemicals
PICCS	:	Philippines Inventory of Chemicals and Chemical Substances
KECI	:	Existing and Evaluated Chemical Substances
AICS	:	Australia Inventory of Chemical Substances
ENCS	:	Existing And New Chemical Substances