

MSDS: Indocyanine Green for Injection USP, Kit.

Material Safety Data Sheet

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Section 1 - IDENTIFICATION

PRODUCT NAME: Indocyanine Green for Injection USP, 25 mg
Description: Indocyanine Green for Injection, USP is a sterile, water soluble, tricarboyanine dye with a peak spectral absorption at 800-810 nm in blood plasma or blood. Indocyanine Green for Injection, USP contains not more than 5.0% sodium iodide. Indocyanine Green for Injection, USP is to be administered intravenously. It is packaged with Sterile Water for Injection, USP used to dissolve the indocyanine green. Indocyanine Green for Injection USP has a pH of approximately 6.5 when reconstituted. Each vial of Indocyanine Green for Injection USP contains 25 mg of indocyanine green as a sterile lyophilized powder.

Product Description: Indocyanine Green for Injection, USP 25 mg and Sterile Water for Injection, USP 10 mL in a kit

Composition:

Active: Indocyanine Green for Injection USP, 25 mg lyophilized powder
Preservative: None
Aqueous Solvent: Sterile Water for Injection, USP 10 mL

Common name of active ingredients: Indocyanine Green, USP
Molecular Formula: $C_{43}H_{47}N_2NaO_6S_2$
Molecular Weight: 774.96 g/mole
CAS No. : 3599-32-4
Legal Category: Prescription only

Section 2 - HAZARDS IDENTIFICATION

Potential Acute Health Effects: Hazardous in case of eye contact (irritant), of ingestion, of inhalation. Anaphylactic or uticular reactions have been reported in patients with or without history of allergy to iodides.

Potential Chronic Health Effects:

Carcinogenic effects: Not available
Mutagenic Effects: Not available

Teratogenic Effects: Not available
 Developmental Toxicity: Not available
 Repeated or prolonged exposure is not known to aggravate medical condition.

Section 3 - FIRST AID MEASURES

Eye Exposure:

Check for and remove any contact lenses. Flush eyes with large volumes of water for 15 or more minutes. Get medical attention immediately.

Skin Exposure:

In case of contact, immediately flush skin with plenty of water. Remove contaminated clothing and shoes. Wash clothing before reuse. Thoroughly clean shoes before reuse. Get medical attention.

Serious Skin Contact:

Not available

Inhalation:

If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

Serious Inhalation:

Not available

Ingestion:

Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. If large quantities of this material are swallowed, call a physician immediately. Loosen tight clothing such as a collar, tie, belt or waistband.

Serious Ingestion:

Not available

Section 4 - FIRE and EXPLOSION DATA

Flammability of the Product: May be combustible at high temperature

Auto-Ignition Temperature: Not available

Flash Points: Not available

Flammable Limits: Not available

Products of Combustion: Carbon oxides (CO, CO₂),
 Nitrogen oxides (NO, NO₂...)
 Sulfur oxides (SO₂, SO₃...).

Fire Hazards in Presence of Various Substances: Not available

Explosion Hazards in Presence of Various Substances:

Risks of explosion of the product in presence of mechanical impact: Not available
 Risks of explosion of the product in presence of static discharge: Not available

Fire Fighting Media and Instructions:

SMALL FIRE: Use DRY chemical powder.

LARGE FIRE: Use water spray, fog or foam. Do not use water jet.

Special Remarks on Fire Hazards: Not available

Special Remarks on Explosion Hazards: Not available

Section 5 - ACCIDENTAL RELEASE MEASURES**Small Spill:**

Use appropriate tools to put the spilled solid in a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and dispose of according to local and regional authority requirements.

Large Spill:

Use a shovel to put the material into a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and allow to evacuate through the sanitary system.

Section 6 - HANDLING AND STORAGE**Steps to be taken in case material is released or spilled:**

See Section 5 above. Wear latex or nitrile gloves and safety glasses when cleaning spills. A dust/mist respirator (N95) may be necessary if excessive aerosols are generated.

Waste Disposal Method:

Incineration in an approved incinerator is recommended. Refer to local, state, and federal rules.

Storage:

Store at controlled room temperature 20° to 25°C (68°F to 77°F).
Keep container tightly closed. Keep container in a cool, well-ventilated area.

Other Precautions:

Indocyanine Green is unstable in aqueous solution and must be used within 6 hours.

Section 7 - EXPOSURE CONTROL / PERSONAL PROTECTION**Engineering Controls:**

Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Personal Protection:

Splash goggles, Lab coat, gloves resistant to chemicals.

Respiratory protection:

If technical exhaust or ventilation measures are not possible or insufficient, respiratory protection must be worn. Fresh air masks are recommended, or combination filters A2-P2 for works of short duration.

General health and safety measures:

The usual precautionary measures for the handling of chemicals have to be observed. Do not eat or drink during work
- no smoking. Wash hands and face before breaks and after work and take a shower if necessary.

Personal Protection in Case of a Large Spill:

Splash goggles. Full suit. Boots. Gloves. Suggested protective clothing might not be sufficient; consult a specialist BEFORE handling this product.

Exposure Limits:

Not available

Section 8 - PHYSICAL & CHEMICAL PROPERTIES

Physical state and appearance:	lyophilized powder
Odor:	Not available
Taste:	Not available
Molecular Weight:	774.96 g/mole
Color:	Green
pH (1% solution/water):	~6
Boiling Point:	Not available
Melting Point:	469.4 - 473 °F (243 - 245 °C) (decomposes >200 °C)
Critical Temperature:	Not available
Specific Gravity:	Approximately 1.000 g/mL
Vapor Pressure:	< 0.0000001 kPa at 25 °C; Negligible.
Vapor Density:	Not available
Volatility:	Not available
Odor Threshold:	Not available
Water/Oil Distribution Coefficient:	-0.29 at pH 7.4
Ionicity (in Water):	Not available
Dispersion Properties:	Not available
Solubility:	Soluble in water
Latex Free:	Yes

Section 9 - STABILITY AND REACTIVITY

Stability:	Stable under normal temperature & pressure
Incompatibility (Materials to Avoid):	Moisture, strong oxidizing agents
Corrosivity:	Non-corrosive in presence of glass
Special Remarks on Reactivity:	Not available
Special Remarks on Corrosivity:	Not available
Polymerization:	Will not occur
Hazardous decomposition products:	Thermal decomposition can lead to the escape of irritating gases and vapors.

Section 10 - TOXICOLOGY INFORMATION

Carcinogenesis, Mutagenesis, Impairment of Fertility:

No studies have been performed to evaluate the carcinogenicity, mutagenicity, or impairment of fertility.

Pregnancy:

Teratogenic Effects:

Pregnancy Category C:

Animal Reproduction studies have not been conducted with Indocyanine Green for Injection USP. It is also not known whether Indocyanine Green for Injection USP can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Indocyanine Green for Injection USP should be given to a pregnant woman only if clearly indicated.

Nursing Mothers:

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Indocyanine Green for Injection USP is administered to a nursing woman.

Pediatric Use:

Safety and effectiveness in pediatric patients have been established.

Geriatric Use:

No overall differences in safety or effectiveness have been observed between elderly and younger patients.

Adverse Reactions:

Anaphylactic or urticarial reactions have been reported in patients with or without history of allergy to iodides. If such reactions occur, treatment with the appropriate agents, e.g., epinephrine, antihistamines, and corticosteroids should be administered.

Over dosage:

There are no data available describing the signs, symptoms, or laboratory findings accompanying overdosage. The LD50 after I.V. administration ranges between 60 and 80 mg/kg in mice, 50 and 70 mg/kg in rats and 50 and 80 mg/kg in rabbits.

Section 11 - ECOLOGICAL INFORMATION

Ecotoxicity: Not available

BOD₅ and COD: Not available

Products of Biodegradation: Possibly hazardous short-term degradation products are not likely. However, long term degradation products may arise.

Toxicity of the Products of Biodegradation:

The products of degradation are more toxic.

Special Remarks on the Products of Biodegradation: Not available

Section 12 - DISPOSAL INFORMATION

Dispose of by incineration at an approved/permitted incinerator.
Review local, state, and federal regulations for your regulatory area.

Section 13 - TRANSPORTATION INFORMATION

DOT Classification: Not a DOT controlled material (United States)

Identification: Not applicable

Special Provisions for Transport: Not applicable

Section 14 - REGULATORY INFORMATION

Federal and State Regulations: TSCA 8(b) inventory: indocyanine green
Other Regulations: Not available
Other Classifications:
WHMIS (Canada): Not controlled under WHMIS (Canada)
DSCL (EEC): R36 - Irritating to eyes
HMIS (U.S.A.):
 Health Hazard: 2
 Fire Hazard: 1
 Reactivity: 0
 Personal Protection: j
National Fire Protection Association (U.S.A.):
 Health: 2
 Flammability: 1
 Reactivity: 0
 Specific hazard:
 Protective Equipment: Splash goggles, lab coat, gloves

Section 15 - OTHER INFORMATION

The information given herein is in good faith and to the best of our knowledge, but no warranty expressed or implied is made

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