



MSDS: IC-Green[®] Sterile Indocyanine Green, USP

Manufacturer: Akorn Incorporated
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Section 1 - IDENTIFICATION

TRADE NAME: IC-Green[®]

Description: IC-Green[®] is a sterile, water soluble, tricarbocyanine dye with a peak spectral absorption at 800-810 nm in blood plasma or blood. IC-Green[®] contains not more than 5.0% sodium iodide. IC-Green[®] is to be administered intravenously. The Aqueous Solvent provided, (pH of 5.5 to 6.5) is a prepared Sterile Water for Injection used to dissolve IC-Green[®].

Product Description: IC-GREEN[®] (indocyanine green for injection, USP) and Aqueous Solvent in a kit

Composition:

Active: Indocyanine Green 25 mg lyophilized powder

Inactive: Sodium Hydroxide to adjust pH

Preservative: None

Aqueous Solvent: Sterile Water for Injection (pH 5.5 to 6.5)

Common name of active ingredients: Indocyanine Green, USP

Molecular Formula: $C_{43}H_{47}N_2NaO_6S_2$

Molecular Weight: 774.96 g/mole

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 uticularial 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, CO ₂), Nitrogen oxides (NO, NO ₂ ...) Sulfur oxides (SO ₂ , SO ₃ ...).	
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:

IC-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

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):	Not available
Boiling Point:	Not available
Melting Point:	Not available
Critical Temperature:	Not available
Specific Gravity:	Approximately 1.000 g/mL
Vapor Pressure:	Not available
Vapor Density:	Not available
Volatility:	Not available
Odor Threshold:	Not available
Water/Oil Distribution Coefficient:	Not available
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

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 IC-GREEN[®]. It is also not known whether IC-GREEN[®] can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. IC-GREEN[®] 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 IC-GREEN[®] 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 overdose. 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

Section 15 - OTHER INFORMATION

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