

SAFETY DATA SHEET

1. Identification

Product Identifier: IC-Green® (indocyanine green for injection, USP)

Synonyms: IC-Green

National Drug Code (NDC): 17478-701-02 (Kit of six 25 mg IC-Green® vials and six 10 mL Aqueous Solvent ampules)
17478-701-10 (Aqueous Solvent ampules, 10 mL fill in 10 mL ampules)
17478-701-25 (IC-Green® vial, 25 mg fill in 20 mL vial)

Recommended Use: Pharmaceutical.

Company: Akorn, Inc.
1925 West Field Court, Suite 300
Lake Forest, Illinois 60045

Contact Telephone: 1-800-932-5676

E mail: customer.service@akorn.com

Emergency Phone Number: CHEMTREC 1-800-424-9300 (U.S. and Canada)

2. Hazard(s) Identification

Physical Hazards: Not classifiable.

Health Hazards: Skin irritation Category 3

Symbol(s): None.

Signal Word: Warning.

Hazard Statement(s): P316 Causes mild skin irritation.

Precautionary Statement(s): P332 If skin irritation occurs: Get medical + advice/attention.
P313

Hazards Not Otherwise Classified: Not classified.

Supplementary Information: None.

3. Composition/Information on Ingredients

Chemical Name	CAS Number	Synonyms	Chemical Formula	Molecular Weight	Percentage
Indocyanine Green	3599-32-4	ICG	C ₄₃ H ₄₇ N ₂ NaO ₆ S ₂	774.96	2.5%

*This formula also contains Sodium Iodide, Sodium Hydroxide and Water for Injection

4. First Aid Measures

Ingestion:	If a person vomits place them in the recovery position so that vomit will not reenter the mouth and throat. Rinse mouth with water. If swallowed, seek medical advice immediately and show the container or label. Treat symptomatically and supportively. Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves.
Eye Contact:	Remove from source of exposure. Flush with copious amounts of water for at least 15 minutes. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
Skin Contact:	Remove from source of exposure. Remove and isolate contaminated clothing and shoes. Flush with copious amounts of water for at least 20 minutes. Use soap. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
Inhalation:	Remove from source of exposure. Move individual(s) to fresh air. Give artificial respiration if individual(s) are not breathing and call emergency medical service. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
Protection of First-Aiders:	Use personal protective equipment (see section 8).
Signs and Symptoms:	Nausea; possible allergic reactions if inhaled, ingested, or in contact with the skin.
Medical Conditions Aggravated by Exposure:	Hypersensitivity to any of the components of the product.
Notes to Physician:	Treat supportively and symptomatically.

5. Firefighting Measures

Suitable Extinguishing Media:	Use extinguishing media for type of surrounding fire.
Unsuitable Extinguishing Media:	Not determined.

Specific Hazards Arising from the Chemical:

- Hazardous Combustion Products:** These products include Carbon Oxides, Hydrogen Iodide, Sodium Oxides, Sulfur Oxides and other hazardous combustion products.
- Other Specific Hazards:** Closed containers may explode from the heat of fire.
- Special Protective Equipment/Precautions for Firefighters:** Wear self-contained breathing apparatus and full and protective gear.

6. Accidental Release Measures

- Personal Precautions:** Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate personal protective equipment and clothing.
- Personal Protective Equipment:** For personal protection see section 8.
- Methods for Cleaning Up:** Dike ahead of liquid spills for later disposal. Absorb with inert material. Recover product and place in an appropriate container for disposal in accordance with local, state and federal regulations.
- Environmental Precautions:** Contain material and prevent release to basement, confined spaces, waterways or soil.
- Reference to Other Sections:** Refer to Sections 8, 12 and 13 for further information.

7. Handling and Storage

- Precautions for Safe Handling:** Handle in accordance with product label and/or product insert information. Handle in accordance with good industrial hygiene and safety practices.
- Conditions for Safe Storage, Including Any Incompatibilities:** Store according to label and/or product insert information. Store away from acids, bases and oxidizers.
- Specific End Use:** Pharmaceuticals.

8. Exposure Controls/Personal Protection**Occupational Exposure Guidelines:**

Common or Chemical Name	Employee Exposure Limits
Indocyanine Green	Not established.
Sodium Iodide	ACGIH TLV: 0.01 mg/m ³ , 8 Hour TWA

- Engineering Controls:** Engineering controls should be used as the primary means to control exposures.

Respiratory Protection:	Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).
Eyes Protection:	Not required for the normal use of this product. Safety glasses with side shields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.
Hand Protection:	Not required for the normal use of this product. Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic non-latex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.
Skin Protection:	Not required for the normal use of this product. Wear protective laboratory coat, apron, or disposable garment when working with large quantities.

9. Physical and Chemical Properties

Physical State/Color:	Solid. Olive-brown, dark-green, blue-green, dark-blue, or black.
Odor:	No data available.
Odor Threshold:	No data available.
pH:	No data available.
Melting Point:	No data available.
Freezing Point:	No data available.
Boiling Point:	No data available.
Flash Point:	No data available.
Evaporation Rate:	No data available.
Flammability (solid, gas):	No data available.
Flammability Limit - Lower:	No data available.
Flammability Limit - Upper:	No data available.
Vapor Pressure:	No data available.
Vapor Density:	No data available.
Relative Density:	No data available.
Solubility(ies):	Miscible in water.
Partition Coefficient (n-octanol/water):	No data available.
Auto-Ignition Temperature:	No data available.
Decomposition Temperature:	No data available.
Viscosity:	No data available.

10. Stability and Reactivity

Reactivity:	No data available.
Chemical Stability:	Stable at normal temperature and pressures.
Possibility of Hazardous Reactions:	No data available.
Conditions to Avoid (e.g., static discharge, shock, or vibration):	No data available.
Incompatible Materials:	No data available.
Hazardous Decomposition Products:	No data available.

11. Toxicological Information**Information on the Likely Routes of Exposure:**

Inhalation:	May be harmful if inhaled. May cause respiratory tract irritation.
Ingestion:	May be harmful if swallowed.
Skin Contact:	May be harmful if absorbed through the skin. May cause irritation.
Eye Contact:	May cause eye irritation.
Symptoms Related to the Physical, Chemical and Toxicological Characteristics:	See Section 4. To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.
Delayed and Immediate Effects of Exposure:	No data available.
Acute Toxicity – Oral:	No data available.
Acute Toxicity – Dermal:	No data available.
Acute Toxicity – Inhalation:	No data available.
Corrosivity:	No data available.
Dermal Irritation:	No data available.
Eye Irritation:	No data available.
Sensitization:	No data available.
Toxicokinetics/Metabolism:	No data available.
Target Organ Effects:	No data available.
Reproductive Effects:	No data available.
Carcinogenicity:	No data available.
National Toxicology Program (NTP):	Not considered to be a carcinogen.
International Agency for Research on Cancer (IARC):	Not considered to be a carcinogen.

Occupational Safety and Health
Administration (OSHA):

Not considered to be a carcinogen.

Mutagenicity:

No data available.

Aspiration Hazard:

No data available.

12. Ecological Information

Ecotoxicity

Aquatic:

No data available.

Terrestrial:

No data available.

Persistence and Degradability:

No data available.

Bioaccumulative Potential:

No data available.

Mobility in Soil:

No data available.

Other Adverse Effects:

No data available.

Other Adverse Effects:

No data available.

13. Disposal Considerations

Dispose of all waste in accordance with Federal, State and Local regulations.

14. Transport Information

UN Number:

Not applicable.

UN Proper Shipping Name:

Not applicable.

Transport Hazard Class(es):

Not applicable.

Packing Group:

Not applicable.

Department of Transportation:

Not regulated as a hazardous material.

**International Air Transport
Association (IATA):**

Not regulated as a dangerous good.

**International Maritime Dangerous
Good (IMDG):**

Not regulated as a dangerous good.

15. Regulatory Information

US Federal Regulations:

**Toxic Substance Control Act
(TSCA):**

This product is a drug regulated by the Food and Drug Administration (FDA), and is not regulated by TSCA.

**CERCLA Hazardous Substance
and Reportable Quantity:**

Not listed.

SARA 313:

Not listed.

SARA 302:

Not listed.

State Regulations

California Proposition 65:

Not listed.

16. Other Information

Not made with natural rubber latex.

NFPA Rating: (Indocyanine Green)

Health: 0
Flammability: 0
Reactivity: 0

HMIS Classification: (Indocyanine Green)

Health: 0
Fire: 0
Physical Hazard: 0

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