

SDS: IC-Green® (indocyanine green for injection)

SAFETY DATA SHEET

1. Identification

Product Identifier:	IC-Green® (Indocyanine Green for Injection) 25 mg
Synonyms:	IC-Green
National Drug Code (NDC):	70100-825-02 (Kit of six vials of IC-Green® 25 mg each and six vials of Sterile Water for Injection USP 10mL each) 0409-4887-17 or 0641-6147-01 or 63323-185-10 (Sterile Water for Injection USP 10mL/vial in 10 mL vial) 70100-725-01 (IC-Green® 25 mg/vial in 25 mL vial)
Recommended Use:	Pharmaceutical
Company:	Renew Pharmaceuticals Limited Athlone Business and Technology Park, Garrycastle Athlone, Co. Westmeath N37 F680, Ireland
Contact Telephone:	+353 90 646 5460
E mail:	info@renewgroup.eu
Emergency Phone Number:	1-844-424-3784

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 P313 Get medical advice/attention
Hazards Not Otherwise Classified:	Not classified
Supplementary Information:	None

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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 g/mole	2.5%

*This formula also contains Sodium Iodide and Water for Injection

4. First Aid Measures

Ingestion:

Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to a unconscious person. 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. Check for and remove any contact lenses. 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. Thoroughly clean shoes before reuse.

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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 (CO, CO ₂), Nitrogen Oxides (NO, NO ₂), Hydrogen, Iodide, Sodium Oxides, Sulfur Oxides (SO ₂ , SO ₃) 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.

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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:

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 in accordance with local, state and federal regulations.

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 dispose of in accordance with local, state and federal regulations.

Absorb liquid spills with inert material. Recover the 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. Wear nitrile gloves and safety glasses when cleaning spills. A dust/mist respirator (N95) may be necessary if excessive aerosols are generated.

Conditions for Safe Storage, Including Any Incompatibilities:

Store at room temperature 20° to 25°C (68°F to 77°F) Keep container tightly closed. Keep container in a cool, well-ventilated area away from acids, bases and oxidizers.

Other Precautions:

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

Specific End Use:

Pharmaceuticals

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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:

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.

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.

Eyes Protection:

Safety glasses with side shields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Maintain eyewash facilities in the work area.

Hand Protection:

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:

Splash goggles, Lab coat, gloves resistant to chemicals

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9. Physical and Chemical Properties

Physical State/Color:	lyophilized powder; dark green
Odor:	No data available.
Odor Threshold:	No data available
pH (1% solution/water):	~6
Melting Point:	469.4 - 473 °F (243 - 245 °C) (decomposes >200°C)
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:	< 0.0000001 kPa at 25 °C; Negligible
Vapor Density:	No data available
Relative Density:	No data available
Solubility(ies):	Soluble in water
Specific Gravity:	Approximately 1.000 g/mL
Partition Coefficient (n-octanol/water):	No data available
Auto-Ignition Temperature:	No data available.
Decomposition Temperature:	No data available
Viscosity:	No data available.
Water/Oil Distribution Coefficient	-0.29 at pH 7.4
Latex Free:	Yes

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10. Stability and Reactivity

Reactivity:	No data available.
Chemical Stability:	Stable at normal temperature and pressure
Possibility of Hazardous Reactions:	No data available.
Conditions to Avoid (e.g., static discharge, shock, or vibration):	No data available.
Incompatible Materials:	Moisture, strong oxidizing agents
Hazardous Decomposition Products:	Thermal decomposition can lead to the escape of irritating gases and vapors
Polymerization:	Will not occur
Corrosivity:	Non-corrosive in the presence of glass

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 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

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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

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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:
SARA 302:**

Not listed
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

Revision Date: 05/01/2025

Revision Number: 1

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