



Zyogreen[®], Indocyanine green 2.5mg/ml

Safety Data Sheet

According to 29 CFR 1910.1200

Date of issue: 2026/03/13

Version: 2.0

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SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Form: Solution for injection

Product Name: Zyogreen[®]

Active substance : Indocyanine green

Chemical name : Sodium 2-[7-[3,3-dimethyl-1-(4-sulfonatobutyl)benz[e]indolin-2-ylidene]hepta-1,3,5-trien-1-yl]-3,3-dimethyl-1-(4-sulfonatobutyl)benz[e]indolinium

1.2. Intended Use of the Product

Identified uses :

ZYOGREEN is indicated for fluorescence imaging :

- Visualization of Vessels, Blood Flow and Tissue Perfusion
- Visualization of Extrahepatic Biliary Ducts
- Lymphatic Mapping of Cervical and Uterine Cancer

ZYOGREEN is indicated for use in ophthalmic angiography in adults and pediatric patients.

Restrictions on use :

Contraindicated in patients with a history of hypersensitivity to indocyanine green.

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

Company	Supplier	Distributor
Provepharm 22 rue Marc Donadille 13013 Marseille, France t: +33 (0)491 086 942 f: +33 (0)491 086 901 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	SAGENT Pharmaceuticals Schaumburg, IL 60173 (USA) Phone: +1 847 908 1600 https://www.sagentpharma.com/

1.4. Emergency Telephone Number

CHEMTREC: 1-800-424-9300 (within USA and Canada), +1 703-527-3887 (outside USA and Canada).

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the Substance or Mixture

Not a hazardous substance or mixture according to the OSHA Hazard Communication Standard (29 CFR 1910.1200).

2.2. Label elements

Not a hazardous substance or mixture according to GHS US classification.

2.3. Other Hazards [HNOC]

Contains Sodium iodide. May produce an allergic reaction.

Contains no PBT or vPvB substances according to REACH No 1907/2006.

This mixture does not contain substances with endocrine disrupting properties in accordance with the criteria laid down in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605.

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SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substance

The product is a mixture.

3.2. Mixture

Name	Product identifier	Quantity/mL	Classification (CLP Classification - According to GB-CLP Regulations UK SI 2019/720 and UK SI 2020/1567)
Indocyanine green	CAS-No : 3599-32-4 EC number: 222-751-5	2.5 mg	Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335 
Water for injection	CAS-No : 7732-18-5 EC number: 231-791-2	q.s. 1 mL	Not Classified

Full text of hazard classes and H-statements: see section 16.
Occupational limits are listed in section 8 if these are available.

SECTION 4: FIRST AID MEASURES

4.1. Description of First Aid Measures

After Inhalation: Remove person to fresh air.

After Skin Contact: Remove contaminated clothing. Flush area with copious quantities of water for 15 minutes.

After Eye Contact: Flush eyes with water as a precaution.

After Ingestion: DO NOT induce vomiting. Flush mouth out with water. Seek medical attention

Protection of First-Aiders: Use personal protective equipment (see section 8).

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

see sections 2 and 11.

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

Always have cardiopulmonary resuscitation personnel and equipment readily available and monitor all patients for hypersensitivity reactions.

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing Media

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

Caution: CO₂ will displace air in confined spaces and may cause an Oxygen deficient atmosphere.

Unsuitable Extinguishing Media: None.

5.2. Special Hazards Arising From the Substance or Mixture

Fire Hazard: Product is not flammable.

Explosion Hazard: Product is not explosive.

Reactivity: Hazardous reactions will not occur under normal conditions.



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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

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

Dispose of in accordance with section 13.

6.4. Reference to Other Sections

See section 8 for information on personal protection equipment.

See section 13 for disposal information.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling

As a general rule, when handling pharmaceutical products, see section 8 for personal protection. Wash the hands thoroughly after handling. Avoid ingestion and inhalation.

Hygiene Measures: Do not eat, drink or smoke during use. Regularly clean equipment, premises and work clothes.

7.2. Conditions for Safe Storage, Including Any Incompatibilities

Keep only in the original container in a dry, cool and well-ventilated place in order to protect from light.

Storage Temperature: Storage temperature at 20°C to 25°C (68°F to 77°F).

Excursions permitted from 15°C to 30°C (59°F to 86°F).

7.3. Specific End Use(s)

Pharmaceutical.

The identified uses for this product are detailed in Section 1.2.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control Parameters

Occupational exposure limits

US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Indocyanine green not listed.

US. OSHA Table Z-1 (29 CFR 1910.1000) : Indocyanine green not listed.

US. OSHA Table Z-2 (29 CFR 1910.1000) : Indocyanine green not listed.

US. OSHA Table Z-3 (29 CFR 1910.1000) : Indocyanine green not listed.

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US. ACGIH Threshold Limit Values : Indocyanine green not listed.

US. NIOSH: Pocket Guide to Chemical Hazards : Indocyanine green not listed.

8.2. Exposure controls

Appropriate engineering controls:

Handle in accordance with good clinical hygiene and safety practice.

Hand protection:

Handle with gloves (Nitrile or latex). Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands. (in accordance with EN374, ASTM F1001 or international equivalent).

Eye protection:

Wear safety glasses or goggles if eye contact is possible (in accordance with EN166, ANSI Z87.1 or international equivalent).

Skin and body protection:

Wear suitable working clothes.

Respiratory protection:

Not required

Control of environmental exposure:

Do not let product enter drains.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on Basic Physical and Chemical Properties

Physical State	:	Liquid
Appearance	:	Deep emerald-green
Odor	:	Solution odorless
Odor Threshold	:	Not concerned
pH	:	No data
Relative Evaporation Rate	:	Not concerned
Melting Point	:	Not concerned
Freezing Point	:	No data
Boiling Point	:	No data
Flash Point	:	No data
Auto-ignition Temperature	:	Not concerned
Decomposition Temperature	:	Not concerned
Flammability (solid, gas)	:	Not concerned
Vapor Pressure	:	No data
Relative Vapor Density at 20 °C	:	No data
Relative Density	:	No data
Specific Gravity	:	Not concerned
Partition coefficient: n-octanol/water	:	No data
Viscosity	:	No data

9.2. Other Information:

Not available.

SECTION 10: STABILITY AND REACTIVITY

- 10.1 Reactivity:**
No dangerous reaction known under conditions of normal use and storage.
- 10.2 Chemical Stability:**
Stable under recommended storage conditions.
- 10.3 Possibility of Hazardous Reactions:**
No dangerous reaction known
- 10.4 Conditions to Avoid:**
Direct rays of the sun.
- 10.5 Incompatible Materials:**
No information available
- 10.6 Hazardous Decomposition Products:**
Carbon Monoxide, Carbon Dioxide may be released by thermal decomposition.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on Toxicological Effects

Acute Toxicity:

Component	CAS No.	LD ₅₀ (intravenous)
Indocyanine green	3599-32-4	60-80 mg/kg (mouse) 50-70 mg/kg (rat) 50-80 mg/kg (rabbit)

Oral, dermal and inhalation : No study available

Skin Corrosion/Irritation:

Anaphylactic or urticarial reactions have been reported in patients with or without history of allergy to iodides.

Serious Eye Damage/Irritation:

Starting from 2.5 mg/mL, ICG (injected into the subretinal space) can produce both structural and functional alterations of the retina in several species (rat, rabbit, cat, and pig).

Respiratory Sensitisation: No study available

Skin Sensitisation: No study available

Germ Cell Mutagenicity: No study available

Carcinogenicity: No study available

Reproductive Toxicity: No study available

Specific Target Organ Toxicity (Single Exposure): No study available

Specific Target Organ Toxicity (Repeated Exposure): No study available

Aspiration Hazard: Not classified

11.2. Information on other hazards

Endocrine disrupting properties:

The product/substance has no endocrine disrupting properties.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecology – General : Not classified

Ecotoxicity effects: No study available

12.2. Persistence and Degradability

Persistence : Soluble in water, Persistence is unlikely, based on information available

12.3. Bioaccumulative Potential

Bioaccumulation is unlikely

12.4. Mobility in Soil

The product is water soluble, and may spread in water systems. Will likely be mobile in the environment due to its water solubility.

12.5. Result of PBT and vPvB assessment

This substance does not meet the criteria for PBT or vPvB according to regulation.

12.6. Endocrine disrupting properties

The product/substance has no endocrine disrupting properties.

12.7. Other adverse effects

No additional information available

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Avoid release to the environment.

Do not mix with other substances. Dispose in a safe manner in accordance with local/national regulations.

Contaminated packing: Properly cleaned container is disposed of according to packaging material.

SECTION 14: TRANSPORT INFORMATION

This product is not classified as dangerous of transport.

14.1 UN number or ID number

-

14.2 UN proper shipping name

DOT: Not dangerous goods

IMDG: Not dangerous goods

IATA: Not dangerous goods

14.3 Transport hazard class(es)

-

14.4 Packing group

-



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14.5 Environmental hazards – MP EmS

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14.6 Special precautions for user

Not relevant

14.7 Maritime transport in bulk according to IMO instruments

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SECTION 15: REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US federal regulations

No further relevant information available.

Sara • Section 355 (extremely hazardous substances): Substance is not listed.

Section 313 (Specific toxic chemical listings): Substance is not listed.

TSCA (Toxic Substances Control Act): ACTIVE

Hazardous Air Pollutants Substance is not listed.

Chemicals known to cause cancer: Substance is not listed.

Chemicals known to cause reproductive toxicity for females: Substance is not listed.

Chemicals known to cause reproductive toxicity for males: Substance is not listed.

Chemicals known to cause developmental toxicity: Substance is not listed.

EPA (Environmental Protection Agency) Substance is not listed.

TLV (Threshold Limit Value) Substance is not listed.

NIOSH-Ca (National Institute for Occupational Safety and Health) Substance is not listed.

International regulations:

X – Listed '-' - Not Listed

Europe (EINECS/ELINCS/NLP), U.S.A. (TSCA), Canada (DSL/NDSL), Philippines (PICCS), Chine (IECSC), Japan (ENCS), Japan (ISHL), Australie (AICS), Korea (KECL).

Name	EINECS	ELINCS	NLP	TSCA	DSL	NDSL	PICCS	IECSC	ENCS	ISHL	AICS	KECL
Indocyanine green (CAS-No : 3599-32-4)	222-751-5	-	-	X	-	X	-	-	-	-	-	-

15.2 Chemical Safety Assessment

For this product, no chemical safety assessment has been carried out.

SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

Revision : 2026/03/13 according to OSHA Hazard Communication Standard (29 CFR 1910.1200).

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Additional information:

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

Descriptions of possible used abbreviations:

CAS : Chemical Abstracts Service (service that maintains the most comprehensive list of chemical substances).

EC50 : Effective Concentration 50 %. The EC50 corresponds to the concentration of a tested substance causing 50 % changes in response (e.g. on growth) during a specified time interval.

ADR : European Agreement Concerning the International Carriage of Dangerous Goods by Road

IMDG : International Maritime Dangerous Goods Code.

IATA : International Civil Aviation Organization/International Air Transport Association

LC50 : Lethal Concentration 50%: the LC50 corresponds to the concentration of a tested substance causing 50 % lethality during a specified time interval.

LD50 : Lethal Dose 50 %: the LD50 corresponds to the dose of a tested substance causing 50 % lethality during a specified time interval.

PBT : Persistent, Bioaccumulative and Toxic.

PNEC : Predicted No-Effect Concentration.

UN RTDG : UN Recommendations on the Transport of Dangerous Good.

vPvB : Very Persistent and very Bioaccumulative.

Full text of H-phrases:

Skin Irrit. 2	Skin irritation (Category 2)
Eye irrit. 2	Eye irritation (Category 2)
STOT SE 3	Specific target organ toxicity – single exposure, category 3
H315	Causes skin irritation
H319	Causes serious eye irritation
H335	May cause respiratory irritation