



<b>Response</b>	Notify radiation safety personnel immediately. The amount of material inhaled should be assessed and documented. The amount of material ingested should be assessed and documented. Wash hands after handling. If exposed or concerned: Get medical advice/attention.
<b>Storage</b>	Store locked up. The vial containing the drug should be kept within its container or within heavier shielding. Avoid contact with the radioactive content. Store away from incompatible materials.
<b>Disposal</b>	Dispose of contents/container in accordance with local/regional/national/international regulations.
<b>Hazard(s) not otherwise classified (HNOC)</b>	None known.
<b>Supplemental information</b>	The contents of the capsule are radioactive. Adequate shielding of the preparation must be maintained at all times.

As per 29 CFR 1910.1200(b)(6)(xi), ionizing and nonionizing radiation are outside the scope and application of the Hazard Communication Standard, although the radioactive material should be considered the principle hazard of the material. This material should only be handled by trained individuals in conformance with the requirements of applicable regulations.

Radioactive materials in the US are not subject to OSHA regulations. The US Nuclear Regulatory Commission (NRC) is the Federal agency responsible protecting the health and safety of the public and the environment by licensing and regulating the civilian uses of the radioactive materials.

CAUTION! RADIOACTIVE MATERIAL. Read Package Insert prior to use. Promptly remove any contamination from the skin, eyes, or clothing. Radioactive drugs must be handled by qualified personnel in conformity with regulations appropriate to the government agency authorized to license the use of this radionuclide. The vial containing the drug should be kept within its container or within heavier shielding. Avoid contact with the radioactive contents which would cause unnecessary exposure to radiation.

### 3. Composition/information on ingredients

#### Mixtures

Chemical name	Common name and synonyms	CAS number	%
Sodium Iodide I-123		41927-88-2	< 0.001
SODIUM THIOSULFATE		7772-98-7	< 0.001
SUCROSE	alpha-D-glucopyranosyl-beta-D-fructofurano side; sugar	57-50-1	~ 100

**Composition comments** All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

### 4. First-aid measures

<b>Inhalation</b>	Remove to fresh air, support breathing by usual methods if necessary. Stand upwind if possible. Evaluate and document the amount of material inhaled and seek medical attention for radiation intake.
<b>Skin contact</b>	Wash off with soap and water. Always blot dry. Do not abrade skin. Notify radiation safety personnel.
<b>Eye contact</b>	Immediately flush eyes with plenty of water for at least 15 minutes. Notify radiation safety personnel.
<b>Ingestion</b>	Notify radiation safety personnel immediately. Rinse mouth. The amount of I-123 in the thyroid gland should be assessed and documented. A thyroid blocking agent may be warranted and administered under the direction of a physician.
<b>Most important symptoms/effects, acute and delayed</b>	Dust may be irritating to eyes and respiratory tract.  Side effects: Serious adverse reactions may include chest pain, tachycardia, rash and hives. Other adverse reactions, although rare, include nausea, vomiting and itching skin.

<b>Indication of immediate medical attention and special treatment needed</b>	Provide general supportive measures and treat symptomatically. Keep victim under observation. Symptoms may be delayed.
	Females of childbearing age and pediatric patients should not be studied unless the benefits anticipated from the performance of the test outweigh the possible risk of exposure to the amount of ionizing radiation associated with the test.
<b>General information</b>	IF exposed or concerned: Get medical advice/attention. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

## 5. Fire-fighting measures

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<b>Flammable properties</b>	Dust may form explosive mixture with air. Dust accumulation from this product may present an explosion hazard in the presence of an ignition source.
<b>Suitable extinguishing media</b>	Use fire-extinguishing media appropriate for surrounding materials.
<b>Unsuitable extinguishing media</b>	None known.
<b>Specific hazards arising from the chemical</b>	Explosion hazard: Avoid generating dust; fine dust dispersed in air in sufficient concentrations and in the presence of an ignition source is a potential dust explosion hazard.
<b>Special protective equipment and precautions for firefighters</b>	As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.
<b>Fire-fighting equipment/instructions</b>	Move containers from fire area if you can do so without risk. Use water spray to cool unopened containers.
<b>Specific methods</b>	Use standard firefighting procedures and consider the hazards of other involved materials.
<b>General fire hazards</b>	May form combustible dust concentrations in air.

## 6. Accidental release measures

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<b>Personal precautions, protective equipment and emergency procedures</b>	Keep unnecessary personnel away. Do not breathe dust. Follow all guidances provided by NRC. In the case of a leak/release of this material, wear protective clothing, a personal respirator, chemical-resistant rubber gloves, chemical safety goggles, and shoe covers. If on site, follow the site licence requirements for the disposal of radioactive material or proceed as directed by the local Radiation Safety Officer. Ventilate the area, allowing sufficient time for several air exchanges. Avoid inhalation of dust from the spilled material. For personal protection, see section 8 of the SDS.
<b>Methods and materials for containment and cleaning up</b>	Stop the flow of material, if this is without risk. Minimize dust generation and accumulation. If possible, place material in a suitable hermetically sealed lead container. Following product recovery, flush area with water. For waste disposal, see section 13 of the SDS.
<b>Environmental precautions</b>	Avoid discharge into drains, water courses or onto the ground.

## 7. Handling and storage

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<b>Precautions for safe handling</b>	Obtain special instructions before use. Provide appropriate exhaust ventilation at places where dust is formed. Minimize dust generation and accumulation. Do not breathe dust. Avoid contact during pregnancy/while nursing. Avoid contact with eyes, skin, and clothing. Avoid prolonged exposure. When using, do not eat, drink or smoke. Wear protective clothing, including chemical safety goggles and chemical-resistant waterproof gloves. Wash hands and forearms after handling. Observe good industrial hygiene practices.
	All shippers and consignees, as well as handlers of this material must possess a valid radioisotope licence issued by the appropriate federal or state authority. Handling time should be kept to a minimum and appropriate radiation shielding should be used. Avoid direct handling by using remote manipulation tools, syringe shields and tongs.
<b>Conditions for safe storage, including any incompatibilities</b>	Store locked up. Store in original tightly closed container. Keep container tightly closed. Store in a well-ventilated place. Store at controlled room temperature 20-25°C (68-77°F). Store away from incompatible materials (see Section 10 of the SDS).
	Storage and disposal of product should be controlled in a manner which is in compliance with the appropriate regulations of the federal or state government agency authorized to license the use of this radionuclide.

## 8. Exposure controls/personal protection

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### Occupational exposure limits

#### U.S. - OSHA

Components	Type	Value	Form
SUCROSE (CAS 57-50-1)	PEL	5 mg/m3	Respirable fraction.
		15 mg/m3	Total dust.
	TWA	5 mg/m3	Respirable fraction.
		15 mg/m3	Total dust.

#### ACGIH

Components	Type	Value
SUCROSE (CAS 57-50-1)	TWA	10 mg/m3

#### U.S. - NIOSH

Components	Type	Value	Form
SUCROSE (CAS 57-50-1)	REL	5 mg/m3	Respirable.
		10 mg/m3	Total

**Biological limit values** No biological exposure limits noted for the ingredient(s).

**Appropriate engineering controls** If engineering measures are not sufficient to maintain concentrations of dust particulates below the Occupational Exposure Limit (OEL), suitable respiratory protection must be worn. Ventilation should be sufficient to effectively remove and prevent buildup of any dusts or fumes that may be generated during handling or thermal processing.

### Individual protection measures, such as personal protective equipment

**Eye/face protection** If contact is likely, safety glasses with side shields are recommended.

#### Skin protection

**Hand protection** Chemical resistant gloves.

**Other** Wear appropriate chemical resistant clothing.

**Respiratory protection** Not expected to require personal respirator usage. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits.

**Thermal hazards** Wear appropriate thermal protective clothing, when necessary.

**General hygiene considerations** When using, do not eat, drink or smoke. Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

## 9. Physical and chemical properties

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**Appearance** Red & white or green & white gelatin capsule.

**Physical state** Solid.

**Form** Capsules.

**Color** Red & white or green & white gelatin capsule.

**Odor** Odorless.

**Odor threshold** Not available.

**pH** Not available.

**Melting point/freezing point** Not available.

**Initial boiling point and boiling range** Not available.

**Flash point** Not available.

**Evaporation rate** Not available.

**Flammability (solid, gas)** Not available.

### Upper/lower flammability or explosive limits

**Flammability limit - lower (%)** Not available.

<b>Flammability limit - upper (%)</b>	Not available.
<b>Explosive limit - lower (%)</b>	Not available.
<b>Explosive limit - upper (%)</b>	Not available.
<b>Vapor pressure</b>	Not available.
<b>Vapor density</b>	Not available.
<b>Relative density</b>	Not available.
<b>Solubility(ies)</b>	
<b>Solubility (water)</b>	Dissolves in water.
<b>Partition coefficient (n-octanol/water)</b>	Not available.
<b>Auto-ignition temperature</b>	Not available.
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not available.
<b>Other information</b>	Specific Activity: 1,933 mCi/μg of Iodine on the calibration date and time.
<b>Half-Life</b>	13.2 hours
<b>Radioactivity</b>	100 & 200 μCi/capsule on the calibration date and time.

## 10. Stability and reactivity

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<b>Reactivity</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.
<b>Chemical stability</b>	Material is stable under normal conditions. In the presence of moist air, a very small fraction of the Sodium Iodide I-123 may break down and emit radioactive fumes containing I-123.
<b>Possibility of hazardous reactions</b>	Will not occur.
<b>Conditions to avoid</b>	Avoid dust formation. Moisture. Heat, flames and sparks. Contact with incompatible materials.
<b>Incompatible materials</b>	Strong oxidizing agents.
<b>Hazardous decomposition products</b>	Carbon dioxide. Carbon monoxide. May emit radioactive fumes containing I-123 when heated to decomposition.

## 11. Toxicological information

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### Information on likely routes of exposure

<b>Ingestion</b>	May cause asymptomatic physiological uptake by thyroid gland or other tissues.
<b>Inhalation</b>	In the presence of moist air, a very small fraction of the Sodium Iodide I-123 may break down and emit radioactive fumes containing I-123. Inhalation of dusts may cause respiratory irritation.
<b>Skin contact</b>	Not expected to produce any acute adverse health effects on contact.
<b>Eye contact</b>	Dust may irritate the eyes.

**Symptoms related to the physical, chemical and toxicological characteristics**      Dust may be irritating to eyes and respiratory tract.

Side effects: Serious adverse reactions may include chest pain, tachycardia, rash and hives. Other adverse reactions, although rare, include nausea, vomiting and itching skin.

### Information on toxicological effects

<b>Acute toxicity</b>	May cause asymptomatic physiological uptake by thyroid gland or other tissues.
<b>Chronic effects</b>	The health risks associated with chronic radiation exposure (cancer, leukemia, genetic and teratogenic effects) are believed to involve levels of radiation exposure which are much higher than those permitted occupationally.

Components	Species	Test Results
SUCROSE (CAS 57-50-1)		
<b>Acute</b>		
<i>Oral</i>		
LD50	Rat	29700 mg/kg
<b>Skin corrosion/irritation</b>	Not classified.	
<b>Serious eye damage/eye irritation</b>	Dust may irritate the eyes.	
<b>Respiratory or skin sensitization</b>		
<b>Respiratory sensitization</b>	Not available.	
<b>Skin sensitization</b>	This product is not expected to cause skin sensitization.	
<b>Germ cell mutagenicity</b>	It is widely accepted by the scientific community that exposure to sufficient quantities of ionizing radiation can potentially cause harmful biological effects which include cancer, leukemia and genetic and teratogenic effects.	
<b>Carcinogenicity</b>	It is widely accepted by the scientific community that exposure to sufficient quantities of ionizing radiation can potentially cause harmful biological effects which include cancer, leukemia and genetic and teratogenic effects.	
<b>ACGIH Carcinogens</b>		
SUCROSE (CAS 57-50-1)	A4 Not classifiable as a human carcinogen.	
<b>Reproductive toxicity</b>	May cause harm to breastfed babies.	
	Since I-123 is excreted in human milk, formulafeeding should be substituted for breast-feeding if the agent must be administered to the mother during lactation.	
<b>Specific target organ toxicity - single exposure</b>	Causes damage to organs (Thyroid).	
<b>Specific target organ toxicity - repeated exposure</b>	Not classified.	
<b>Aspiration hazard</b>	Due to partial or complete lack of data the classification is not possible.	
<b>Further information</b>	Females of childbearing age and pediatric patients should not be studied unless the benefits anticipated from the performance of the test outweigh the possible risk of exposure to the amount of ionizing radiation associated with the test.	

## 12. Ecological information

<b>Ecotoxicity</b>	The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.	
<b>Components</b>		
SODIUM THIOSULFATE (CAS 7772-98-7)		
<b>Aquatic</b>		
Fish	LC50	Western mosquitofish ( <i>Gambusia affinis</i> ) 24000 mg/l, 96 hours
<b>Persistence and degradability</b>	No data is available on the degradability of this product.	
<b>Bioaccumulative potential</b>		
<b>Partition coefficient n-octanol / water (log Kow)</b>		
SUCROSE		-3.7
<b>Mobility in soil</b>	No data available.	
<b>Other adverse effects</b>	None known.	

## 13. Disposal considerations

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<b>Disposal instructions</b>	Sodium Iodide I-123 Diagnostic Capsules are Radioactive Waste until the activity has decayed to non-detectable levels. Radioactive waste must be handled in accordance with procedures established by your Radiation Safety Officer, NRC and other applicable regulations. If medical waste is involved, such as blood, blood products, or sharps, the waste must be handled as a biohazard and disposed of accordingly. If not a biohazard, consult local, state and federal regulations for proper disposal.
<b>Local disposal regulations</b>	Dispose in accordance with all applicable regulations.
<b>Hazardous waste code</b>	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
<b>Waste from residues / unused products</b>	Dispose of in accordance with local regulations.
<b>Contaminated packaging</b>	Dispose in accordance with all applicable regulations.

## 14. Transport information

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### DOT

<b>UN number</b>	UN2915
<b>UN proper shipping name</b>	Radioactive material, Type A package
<b>Transport hazard class(es)</b>	
<b>Class</b>	7
<b>Subsidiary risk</b>	-
<b>Label(s)</b>	7
<b>Packing group</b>	Not applicable.
<b>Special precautions for user</b>	Read safety instructions, SDS and emergency procedures before handling.
<b>Special provisions</b>	A56, W7, W8
<b>Packaging exceptions</b>	None
<b>Packaging non bulk</b>	415, 418, 419
<b>Packaging bulk</b>	415, 418, 419

### IATA

<b>UN number</b>	UN2915
<b>UN proper shipping name</b>	Radioactive material, Type A package
<b>Transport hazard class(es)</b>	
<b>Class</b>	7
<b>Subsidiary risk</b>	-
<b>Packing group</b>	Not applicable.
<b>Environmental hazards</b>	No.
<b>ERG Code</b>	7L
<b>Special precautions for user</b>	Read safety instructions, SDS and emergency procedures before handling.
<b>Other information</b>	
<b>Passenger and cargo aircraft</b>	Allowed.
<b>Cargo aircraft only</b>	Allowed.

### IMDG

<b>UN number</b>	UN2915
<b>UN proper shipping name</b>	Radioactive material, Type A package
<b>Transport hazard class(es)</b>	
<b>Class</b>	7
<b>Subsidiary risk</b>	-
<b>Label(s)</b>	7
<b>Packing group</b>	Not applicable.
<b>Environmental hazards</b>	
<b>Marine pollutant</b>	No.
<b>EmS</b>	Not available.
<b>Special precautions for user</b>	Read safety instructions, SDS and emergency procedures before handling.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable.

DOT; IATA; IMDG



## 15. Regulatory information

### US federal regulations

Radioactive materials in the US are not subject to OSHA regulations. The US Nuclear Regulatory Commission (NRC) is the Federal agency responsible protecting the health and safety of the public and the environment by licensing and regulating the civilian uses of the radioactive materials.

#### TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

#### CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

#### SARA 304 Emergency release notification

Not regulated.

#### OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

### Superfund Amendments and Reauthorization Act of 1986 (SARA)

#### Hazard categories

Immediate Hazard - Yes  
Delayed Hazard - Yes  
Fire Hazard - No  
Pressure Hazard - No  
Reactivity Hazard - No

#### SARA 302 Extremely hazardous substance

Not listed.

#### SARA 311/312 Hazardous chemical

Yes

### Other federal regulations

#### Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

#### Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

#### Safe Drinking Water Act (SDWA)

Not regulated.

### US state regulations

#### US. Massachusetts RTK - Substance List

SUCROSE (CAS 57-50-1)

#### US. New Jersey Worker and Community Right-to-Know Act

Not listed.

#### US. Pennsylvania Worker and Community Right-to-Know Law

SUCROSE (CAS 57-50-1)



## US. Rhode Island RTK

Not regulated.

## US. California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

### International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

\*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

### 16. Other information, including date of preparation or last revision

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<b>Revision Information</b>	Product and Company Identification: Synonyms Hazard(s) identification: Supplemental information Composition / Information on Ingredients: Ingredients Accidental release measures: Personal precautions, protective equipment and emergency procedures Physical & Chemical Properties: Multiple Properties Toxicological Information: Toxicological Data HazReg Data: North America GHS: Qualifiers