

1. Identification

Product identifier	Sodium Iodide I 131 Solution	
Other means of identification		
SDS number	SISOL	
Synonyms	I 131 solution	
Recommended use	The content of this kit as sold is radioactive.	
	Sodium Iodide I 131 Solution Therapeutic is a radioactive therapeutic agent indicated for the treatment of hyperthyroidism and thyroid carcinomas that take up iodine. Palliative effects may be observed in patients with advanced thyroid malignancy if the metastatic lesions take up iodine.	
Recommended restrictions	None known.	
Manufacturer/Importer/Supplier/Distributor information		
Manufacturer		
Manufacturer		
Company name	Mallinckrodt Nuclear Medicine LLC	
Address	2703 Wagner Place Maryland Heights, MO 63043 United States	
Telephone number	Customer Service 888-744-1414	
Emergency telephone number	24 Hour Emergency 314-654-1600 Chemtrec 800-424-9300	

2. Hazard(s) identification

Physical hazards	Not classified.	
Health hazards	Germ cell mutagenicity	Category 1B
	Carcinogenicity	Category 1B
	Reproductive toxicity	Category 1B
	Reproductive toxicity	Effects on or via lactation
	Specific target organ toxicity, single exposure	Category 1 (Thyroid)
	Specific target organ toxicity, repeated exposure	Category 1 (Thyroid, Bone marrow, Heart, Blood)
Environmental hazards	Not classified.	
OSHA defined hazards	Not classified.	
Labeling		
Contains	DISODIUM EDTA, SODIUM BISULFITE, Sodium Iodide I 131, SODIUM PHOSPHATE, DIBASIC, WATER	

Label elements



Signal word

Danger

Hazard statement

May cause cancer. May cause genetic defects. May damage fertility or the unborn child. May cause harm to breast-fed children. Causes damage to organs (Thyroid). Causes damage to organs (Thyroid, Bone marrow, Heart, Blood) through prolonged or repeated exposure.

RADIOACTIVE MATERIAL HANDLE ACCORDING TO ALL FEDERAL AND STATE REGULATIONS GOVERNING THE USE OF RADIOACTIVE MATERIAL

Precautionary statement**Prevention**

Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not breathe mist or vapor. Do not eat, drink or smoke when using this product. Avoid contact during pregnancy/while nursing. Wear protective gloves/protective clothing/eye protection/face protection. Wash thoroughly after handling.

Response

If exposed or concerned: Get medical advice/attention.

Storage

Store locked up. Store away from incompatible materials.

Disposal

Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazard(s) not otherwise classified (HNOC)

None known.

Supplemental information

Unwanted radiation exposure can occur from handling and administration of radiopharmaceuticals or from contaminated waste products, including urine and feces. Follow safe administration instructions to minimize unnecessary radiation exposure to patients and health care workers.

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	%
WATER	HYDROGEN OXIDE DIHYDROGEN OXIDE WATER, DISTILLED	7732-18-5	99.2
SODIUM PHOSPHATE, DIBASIC	DISODIUM PHOSPHATE DISODIUM HYDROGEN PHOSPHATE DSP	7558-79-4	0.5
DISODIUM EDTA		139-33-3	0.2
SODIUM BISULFITE		7631-90-5	0.1
Sodium Iodide I 131		7790-26-3	< 0.001

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**Inhalation**

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.

Skin contact

Wash off with soap and water. Always blot dry. Do not abrade skin. Notify radiation safety personnel.

Eye contact

Immediately flush eyes with plenty of water for at least 15 minutes. Notify radiation safety personnel.

Ingestion	Notify radiation safety personnel immediately. Rinse mouth. The amount of I 131 in the thyroid gland should be assessed and documented. A thyroid blocking agent may be warranted and administered under the direction of a physician.
Most important symptoms/effects, acute and delayed	<p>Direct contact with eyes may cause temporary irritation.</p> <p>Serious adverse reactions include radiation-induced thyroiditis, thyroid-stimulating hormone and thyroid enlargement, radiation-induced toxicities, hypersensitivity reactions, fetal risk, transient infertility and radiation exposure to other individuals.</p> <p>Radiation-related adverse reactions are a function of the dose level received by the patient.</p> <p>Adverse reactions that have been reported with doses of sodium iodide I-131 used in the treatment of benign disease include sialadenitis, chest pain, tachycardia, iododerma, itching skin, rash, hives, hypothyroidism, hyperthyroidism, thyrotoxic crisis, hypoparathyroidism, and local swelling.</p> <p>Adverse reactions that have been reported with doses of sodium iodide I-131 used in the treatment of malignant disease include radiation sickness, bone marrow depression, anemia, leucopenia, thrombocytopenia, blood dyscrasia, leukemia, solid cancers, lacrimal gland dysfunction, salivary gland dysfunction, nausea, vomiting, congenital hypothyroidism, and chromosomal abnormalities.</p> <p>Adverse reactions that occur after treatment of benign disease may also occur after treatment of malignant disease. Tenderness, pain on swallowing, sore throat, and cough have been reported, generally around the third day after sodium iodide I-131 administration.</p>
Indication of immediate medical attention and special treatment needed	Provide general supportive measures and treat symptomatically. Keep victim under observation. Symptoms may be delayed.
General information	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

Flammable properties	None known.
Suitable extinguishing media	Use fire-extinguishing media appropriate for surrounding materials.
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	During fire, gases hazardous to health may be formed. A very small fraction of the Sodium Iodide I 131 solution may break down and emit radioactive fumes containing I 131.
Special protective equipment and precautions for firefighters	As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.
Fire-fighting equipment/instructions	Move containers from fire area if you can do so without risk. Use water spray to cool unopened containers.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Do not breathe mist or vapor. 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. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.
Methods and materials for containment and cleaning up	Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible. Cover with plastic sheet to prevent spreading. Absorb in vermiculite, dry sand or earth and place into containers. If possible, place material in a suitable hermetically sealed lead container. Clean surface thoroughly to remove residual contamination. Following product recovery, flush area with water. For waste disposal, see section 13 of the SDS.
Environmental precautions	Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling

Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Follow all guidances provided by the US Nuclear Regulatory Commission or equivalent authority and your radiation safety personnel. Maintain radioactive exposures as low as reasonably achievable. 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. Provide adequate ventilation. Do not breathe mist or vapor. Do not get in eyes, on skin, on clothing. Avoid contact during pregnancy/while nursing. Avoid prolonged exposure. When using, do not eat, drink or smoke. Should be handled in closed systems, if possible. Wear protective clothing, including chemical safety goggles and chemical-resistant waterproof gloves. Wash hands and forearms after handling. Observe good industrial hygiene practices.

Conditions for safe storage, including any incompatibilities

Store locked up. Store in original tightly closed container. 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

Occupational exposure limits

US. ACGIH Threshold Limit Values

Components	Type	Value	Form
SODIUM BISULFITE (CAS 7631-90-5)	TWA	5 mg/m ³	
Sodium Iodide I 131 (CAS 7790-26-3)	TWA	0.01 ppm	Inhalable fraction and vapor.

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value
SODIUM BISULFITE (CAS 7631-90-5)	TWA	5 mg/m ³

Biological limit values

No biological exposure limits noted for the ingredient(s).

Appropriate engineering controls

Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

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. Use of an impervious apron is recommended.

Respiratory protection

Not expected to require personal respirator usage.

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

Appearance

Clear, colorless liquid in a 10 mL French-square, glass, screw-cap vial.

Physical state

Liquid.

Form

Solution.

Color

Colorless.

Odor	Odorless.
Odor threshold	Not available.
pH	Not available.
Melting point/freezing point	32 °F (0 °C)
Initial boiling point and boiling range	212 °F (100 °C)
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not available.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	Not available.
Vapor density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Soluble in water.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	Specific Activity: 124 mCi/μg of Iodine on the calibration date and time.
Concentration	3.5, 5.0 or 25.0 mCi/mL on the calibration date and time.
Half-Life	8.04 hours
Radioactivity	From 3.5 to 150 mCi/vial on the calibration date and time.

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions. A very small fraction of the Sodium Iodide I 131 solution may break down and emit radioactive fumes containing I 131.
Possibility of hazardous reactions	Will not occur.
Conditions to avoid	Contact with incompatible materials.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	May emit radioactive fumes containing I 131 when heated to decomposition.

11. Toxicological information

Information on likely routes of exposure

Ingestion	May cause asymptomatic physiological uptake by thyroid gland or other tissues.
Inhalation	A very small fraction of the Sodium Iodide I 131 solution may break down and emit radioactive fumes containing I 131. Not expected to produce any acute adverse health effects on inhalation. No respiratory symptoms.
Skin contact	Not expected to produce any acute adverse health effects on contact.

Eye contact
Symptoms related to the physical, chemical and toxicological characteristics

Direct contact with eyes may cause temporary irritation.

Direct contact with eyes may cause temporary irritation.

Serious adverse reactions include radiation-induced thyroiditis, thyroid-stimulating hormone and thyroid enlargement, radiation-induced toxicities, hypersensitivity reactions, fetal risk, transient infertility and radiation exposure to other individuals.

Radiation-related adverse reactions are a function of the dose level received by the patient.

Adverse reactions that have been reported with doses of sodium iodide I-131 used in the treatment of benign disease include sialadenitis, chest pain, tachycardia, iododerma, itching skin, rash, hives, hypothyroidism, hyperthyroidism, thyrotoxic crisis, hypoparathyroidism, and local swelling.

Adverse reactions that have been reported with doses of sodium iodide I-131 used in the treatment of malignant disease include radiation sickness, bone marrow depression, anemia, leucopenia, thrombocytopenia, blood dyscrasia, leukemia, solid cancers, lacrimal gland dysfunction, salivary gland dysfunction, nausea, vomiting, congenital hypothyroidism, and chromosomal abnormalities.

Adverse reactions that occur after treatment of benign disease may also occur after treatment of malignant disease. Tenderness, pain on swallowing, sore throat, and cough have been reported, generally around the third day after sodium iodide I-131 administration.

Information on toxicological effects

Acute toxicity

May cause asymptomatic physiological uptake by thyroid gland or other tissues.

Chronic effects

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
SODIUM BISULFITE (CAS 7631-90-5)		
Acute		
<i>Oral</i>		
LD50	Rat	2 g/kg
Skin corrosion/irritation	Not classified.	
Serious eye damage/eye irritation	Direct contact with eyes may cause temporary irritation.	
Respiratory or skin sensitization		
Respiratory sensitization	Sodium iodide I-131 capsules may contain sodium bisulfite, a sulfite that may cause allergic-type reactions, including anaphylactic symptoms and life-threatening or less severe asthmatic episodes. The overall prevalence of sulfite sensitivity in the general population is unknown and probably low. Sulfite sensitivity is seen more frequently in asthmatic than in nonasthmatic people.	
Skin sensitization	Reactions, including rash and hives have been reported following administration of sodium iodide I-131.	
Germ cell mutagenicity	May cause genetic defects.	
	Congenital, familial and genetic disorders: congenital hypothyroidism and chromosomal abnormalities.	
Carcinogenicity	May cause cancer.	
	Neoplasms benign, malignant and unspecified (including cysts and polyps): leukemia and solid cancers.	

ACGIH Carcinogens

SODIUM BISULFITE (CAS 7631-90-5)

A4 Not classifiable as a human carcinogen.

IARC Monographs. Overall Evaluation of Carcinogenicity

SODIUM BISULFITE (CAS 7631-90-5)

3 Not classifiable as to carcinogenicity to humans.

Reproductive toxicity

May cause harm to breastfed babies. May damage fertility or the unborn child.

Sodium iodide I-131 is excreted into human milk and may reach concentrations equal to or greater than concentrations in maternal plasma. To minimize the absorbed radiation dose to the breast tissue, breastfeeding and breast-pumping should be discontinued for at least four weeks before administration of sodium iodide I-131. Sodium iodide I-131 is contraindicated in pregnancy; if sodium iodide I-131 is administered in the postpartum period, the lactating mother should not breast-feed the infant. Breastfeeding may resume with the birth of another child, if the mother does not receive sodium iodide I-131 during that postpartum period.

Transplacental passage of sodium iodide I-131 can cause severe and possibly irreversible hypothyroidism in neonates.

Transient, dose-related impairment of testicular function has been reported after sodium iodide I-131 therapy. Consider sperm banking for men who are anticipated to receive a high cumulative sodium iodide I-131 dose (e.g., greater than 14 GBq). In females, transient ovarian failure has been observed after sodium iodide I-131 therapy.

Specific target organ toxicity - single exposure

Causes damage to organs (Thyroid).

Specific target organ toxicity - repeated exposure

Causes damage to organs (Thyroid, Bone marrow, Heart, Blood) through prolonged or repeated exposure.

Aspiration hazard

Due to partial or complete lack of data the classification is not possible.

12. Ecological information**Ecotoxicity**

This material has not been tested for environmental effects.

Components**Species****Test Results**

SODIUM BISULFITE (CAS 7631-90-5)

Aquatic

Fish

LC50

Western mosquitofish (*Gambusia affinis*) 240 mg/l, 96 hours**Persistence and degradability**

No data is available on the degradability of this product.

Bioaccumulative potential

No data available.

Mobility in soil

No data available.

Other adverse effects

An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.

13. Disposal considerations**Disposal instructions**

Sodium Iodide I 131 Oral Therapeutic Solution is 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.

Local disposal regulations

Dispose in accordance with all applicable regulations.

Hazardous waste code

The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

Waste from residues / unused products

Dispose of in accordance with local regulations.

Contaminated packaging

Dispose in accordance with all applicable regulations.

14. Transport information

DOT

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

IATA

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

IMDG

UN number	UN2915
UN proper shipping name	Radioactive material, Type A package
Transport hazard class(es)	
Class	7
Subsidiary risk	-
Label(s)	7
Packing group	Not applicable.
Environmental hazards	
Marine pollutant	No.
EmS	Not available.
Special precautions for user	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)

SODIUM BISULFITE (CAS 7631-90-5) Listed.

SODIUM PHOSPHATE, DIBASIC (CAS 7558-79-4) Listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

CERCLA (Superfund) reportable quantity

SODIUM BISULFITE: 5000.0000

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

SODIUM BISULFITE (CAS 7631-90-5)

SODIUM PHOSPHATE, DIBASIC (CAS 7558-79-4)

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

SODIUM BISULFITE (CAS 7631-90-5)

SODIUM PHOSPHATE, DIBASIC (CAS 7558-79-4)

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

SODIUM BISULFITE (CAS 7631-90-5)

SODIUM PHOSPHATE, DIBASIC (CAS 7558-79-4)

US. Rhode Island RTK

SODIUM BISULFITE (CAS 7631-90-5)

SODIUM PHOSPHATE, DIBASIC (CAS 7558-79-4)

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

Country(s) or region	Inventory name	On inventory (yes/no)*
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	Yes
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	Yes

*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

Issue date 01-21-2016

Version # 01

Disclaimer

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Revision Information

Product and Company Identification: Synonyms
Composition / Information on Ingredients: Ingredients
Physical & Chemical Properties: Multiple Properties
Toxicological Information: Toxicological Data
Regulatory Information: United States
HazReg Data: North America
GHS: Classification