

1. Identification

| | | |
|---|--|--|
| Product identifier | Sodium Iodide I 131 Capsules Therapeutic | |
| Other means of identification | | |
| SDS number | SICAP | |
| Synonyms | I 131 therapeutic capsules. | |
| Recommended use | Sodium Iodide I 131 Capsules Therapeutic is a radioactive therapeutic agent indicated for the treatment of hyperthyroidism and thyroid carcinomas that 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 Sodium Iodide I 131, SODIUM PHOSPHATE, DIBASIC

Label elements



Signal word Danger

Hazard statement May cause genetic defects. May cause cancer. May damage fertility or the unborn child. Causes damage to organs (Thyroid). May cause harm to breast-fed children. 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 | % |
|---------------------------|--|------------|---------|
| Sodium Iodide I 131 | | 7790-26-3 | < 0.001 |
| SODIUM PHOSPHATE, DIBASIC | DISODIUM PHOSPHATE DISODIUM HYDROGEN PHOSPHATE DSP | 7558-79-4 | ~ 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

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

Dust may be irritating to eyes and respiratory tract.

Serious adverse reactions include radiation-induced thyroiditis, thyroid-stimulating hormone and thyroid enlargement, radiation-induced toxicities, hypersensitivity reactions, fetal risk 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.

Indication of immediate medical attention and special treatment needed

Provide general supportive measures and treat symptomatically. Keep victim under observation. Symptoms may be delayed.

Radiation-induced thyroiditis: may cause or worsen hyperthyroidism; consider pre-treatment with antithyroid medications.

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 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.

Methods and materials for containment and cleaning up

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.

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. 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. 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. 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.

Conditions for safe storage, including any incompatibilities

Store locked up. Store in closed original container at temperatures between 15°C and 30°C. Store in a well-ventilated place. 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 Iodide I 131 (CAS 7790-26-3) | TWA | 0.01 ppm | Inhalable fraction and vapor. |

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

Appearance

Opaque, white gelatin capsules in a 10 mL French-square, glass, screw-cap vial.

Physical state

Solid.

Form

Capsules.

Color

Opaque, white gelatin capsules in a 10 mL French-square, glass, screw-cap vial.

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. |
| 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) | Dissolves 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. |
| Half-Life | 8.04 days |
| Radioactivity | From 0.75 to 100 mCi/capsule 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. In the presence of moist air, a very small fraction of the Sodium Iodide I 131 may break down and emit radioactive fumes containing I 131. |
| Possibility of hazardous reactions | Will not occur. |
| Conditions to avoid | Avoid dust formation. Moisture. Contact with incompatible materials. |
| Incompatible materials | Strong oxidizing agents. |
| Hazardous decomposition products | Sodium oxides. Oxides of phosphorus. 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 | In the presence of moist air, a very small fraction of the Sodium Iodide I 131 may break down and emit radioactive fumes containing I 131. Inhalation of dusts may cause respiratory irritation. |
| Skin contact | Not expected to produce any acute adverse health effects on contact. |
| Eye contact | Dust may irritate the eyes. |

Symptoms related to the physical, chemical and toxicological characteristics

Dust may be irritating to eyes and respiratory tract.

Serious adverse reactions include radiation-induced thyroiditis, thyroid-stimulating hormone and thyroid enlargement, radiation-induced toxicities, hypersensitivity reactions, fetal risk 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.

| Product | Species | Test Results |
|--|---|--|
| Sodium Iodide I 131 Capsules Therapeutic | | |
| Acute | | |
| <i>Oral</i> | | |
| LD50 | Rat | 17.0002 g/kg estimated |
| Skin corrosion/irritation | Not classified. | |
| Serious eye damage/eye irritation | Dust may irritate the eyes. | |
| 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 Iodide I 131 (CAS 7790-26-3) | | A4 Not classifiable as a human carcinogen. |

| | |
|---|--|
| 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. |
| Further information | Post-marketing reports have identified an increased risk for neoplasia, as well as risks for hematopoietic suppression. Salivary and lacrimal gland toxicity is relatively common and may manifest as conjunctivitis, xerophthalmia, epiphora, sialadenitis and xerostomia. |

12. Ecological information

| | |
|--------------------------------------|---|
| Ecotoxicity | This material has not been tested for environmental effects. |
| 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 Therapeutic Capsules are Radioactive Waste until the activity has decayed to nondetectable 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 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.

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 PHOSPHATE, DIBASIC (CAS 7558-79-4)

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

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

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

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

US. Rhode Island RTK

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 |
| 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 |

| | | |
|-----------------------------|---|-------------------------------|
| Country(s) or region | Inventory name | On inventory (yes/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 Mallinckrodt provides the information contained herein in good faith but makes no representation as to its comprehensiveness or accuracy. This document is intended only as a guide to the appropriate precautionary handling of the material by a properly trained person using this product. Individuals receiving the information must exercise their independent judgment in determining its appropriateness for a particular purpose. MALLINCKRODT MAKES NO REPRESENTATIONS OR WARRANTIES, EITHER EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE WITH RESPECT TO THE INFORMATION SET FORTH HEREIN OR THE PRODUCT TO WHICH THE INFORMATION REFERS. ACCORDINGLY, MALLINCKRODT WILL NOT BE RESPONSIBLE FOR DAMAGES RESULTING FROM USE OF OR RELIANCE UPON THIS INFORMATION.

Revision Information Product and Company Identification: Synonyms
 Composition / Information on Ingredients: Ingredients
 Accidental release measures: Personal precautions, protective equipment and emergency procedures
 Physical & Chemical Properties: Multiple Properties
 Transport Information: Proper Shipping Name/Packing Group
 HazReg Data: North America
 GHS: Qualifiers