MATERIAL SAFETY DATA SHEET

SODIUM IODIDE I 131 THERAPEUTIC CAPSULES

SECTION 1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Product Name: Sodium Iodide I 131 Therapeutic Capsules.
Synonyms: I 131 therapeutic capsules.
Manufacturer: **Mallinckrodt Inc.**
2703 Wagner Place
Maryland Heights, MO 63043

Revision Date: January 1, 2003
Information Telephone Number: (888) 744-1414
Emergency Telephone Number: (314) 654-7860
CHEMTREC: 1-800-424-9300
CANUTEC: 613-996-6666

SECTION 2. COMPOSITION, INFORMATION ON INGREDIENTS

Chemical Ingredients:

Component	CAS #	Wt %
Sodium Iodide I 131	7790-26-3	< 0.001%
Sodium Phosphate, Dibasic	7558-79-4	~ 100%

SECTION 3. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

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.

POTENTIAL HEALTH EFFECTS

Inhalation:
In the presence of moist air, a very small fraction of Sodium Iodide I 131 may break down and emit radioactive fumes containing I 131. Inhalation of sodium phosphate may irritate the respiratory tract.

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

Skin Contact:
Not expected to produce any acute adverse health effects.

Eye Contact:
No adverse effect expected, but sodium phosphate may irritate the eyes.

Chronic Exposure:
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.

Aggravation of Pre-existing Conditions:
No information found.

SECTION 4. FIRST AID MEASURES

Inhalation:
Notify radiation safety personnel immediately. The amount of material inhaled should be assessed and documented.

Ingestion:
Notify radiation safety personnel immediately. 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.

Skin Exposure:
If skin contact occurs, wash the affected area thoroughly with soap and water until no more radioactivity can be removed. Always blot dry. Do not abrade skin. Notify radiation safety personnel.

Eye Exposure:
If a splash occurs, wash eyes with water for at least 15 minutes or until no more radioactivity can be removed. Notify radiation safety personnel.

SECTION 5. FIRE FIGHTING MEASURES

Fire: Not considered to be a fire hazard.

Explosion: Not considered to be an explosion hazard.

Fire Extinguishing Media: Use any means suitable for extinguishing surrounding fire.

Special Instructions: In the event of a fire, wear full protective clothing and NIOSH-approved self-contained breathing apparatus with full facepiece operated in the pressure demand or other positive pressure mode.

SECTION 6. ACCIDENTAL RELEASE MEASURES

If the product is received in a leaking condition or any loss or release of the radioactive contents occurs, notify your Radiation Safety Department and Mallinckrodt at (314) 654-7860. All cleanup operations should be performed according to the Standard Operating Procedures (SOPs) established for your facility and by the NRC or other applicable local, state or federal regulations.

SECTION 7. HANDLING AND STORAGE

Store at 15°C to 30°C. Handling time should be kept to a minimum and appropriate shielding should be used. Handling devices such as syringe shields and tongs should be used. 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.

SECTION 8. EXPOSURE CONTROLS, PERSONAL PROTECTION

Airborne Exposure Limits:
–NRC Occupational concentration limit is 2×10^{-8} µCi/mL of air.

Engineering Controls:
Properly sealed containers are not expected to require any special ventilation.

Respiratory Protection:
Not expected to require personal respirator usage.

Skin Protection:
Disposable plastic, latex, or rubber gloves; labcoat.

Eye/Face Protection:
Safety glasses.

Precautions:
No smoking, eating, or drinking should be allowed in any area where radioactive materials are handled or stored.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

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

Odor: Odorless.

Solubility: Dissolves in water.

Radioactivity: From 0.75 to 100 mCi/capsule on the calibration date and time.

Specific Activity: 124 mCi/μg of Iodine on the calibration date and time.

Half-Life: ca. 8.04 days.

SECTION 10. STABILITY AND REACTIVITY

Stability: Stable under ordinary conditions of use and storage. 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.

Hazardous Decomposition Products: May emit sodium and phosphorus oxides, and radioactive fumes containing I 131 when heated to decomposition.

Hazardous Polymerization: Will not occur.

Incompatibilities: No information found.

SECTION 11. TOXICOLOGICAL INFORMATION

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. The uptake of I 131 can result in slight to total thyroid dysfunction. For detailed toxicological information on specific components, write to the address listed in Section 1 - Attn: Regulatory Compliance Department.

SECTION 12. ECOLOGICAL INFORMATION

Because this product is intended for use by hospital or clinic patients, it is expected to be treated by standard wastewater treatment facilities with no adverse environmental impacts.

SECTION 13. DISPOSAL CONSIDERATIONS

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 radioactive or a biohazard, waste Sodium Iodide I 131 Therapeutic Capsules are considered non-hazardous. Consult local, state and federal regulations for proper disposal.

SECTION 14. TRANSPORT INFORMATION

DOT (Department of Transportation):

Proper Shipping Name: Radioactive Material, n.o.s.

Hazard Class: 7

Identification Number: UN2982

RQ: Shipments of 10mCi or more per package must have "RQ" marked on the package exterior and on the shipping papers.

SECTION 15. REGULATORY INFORMATION

CERCLA Reportable Quantities:
I 131 = 0.01 Ci (3.7 E 8 Bq); Sodium Phosphate, Dibasic = 5,000 lbs.
Releases to air, land or water of these hazardous substances which exceed the Reportable Quantity (RQ) must be reported to the National Response Center at 800-424-8802.
SARA Title III
302 Extremely Hazardous Substances: None
311/312 Hazard Categories: Acute, Chronic.
313 Toxic substances subject to annual release reporting requirements: None.
RCRA Hazardous Waste Status
Non-hazardous (See Section 13 for additional details.)
California Proposition 65 Warning
This product contains a substance known to the State of California to cause cancer and reproductive toxicity
Australian Hazchem Code: None allocated.
Australian Poison Schedule: None allocated.
WHMIS: This MSDS has been prepared according to the hazard criteria of the Controlled Products Regulations (CPR) and the MSDS contains all of the information required by the CPR.

SECTION 16. OTHER INFORMATION

MSDS Status: Revised in accordance with ANSI Guideline Z400.1-1998
NFPA Ratings: Health: 1 Flammability: 0 Reactivity: 0
Product Use: Diagnostic imaging agent
Revision Information: Section 8 updated.

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