



MATERIAL SAFETY DATA SHEET

Sodium Iodide I 131 Capsule, USP, Diagnostic Oral

SECTION 1. CHEMICAL PRODUCT & COMPANY IDENTIFICATION

Product Name: Sodium Iodide I 131 Capsule, USP, Diagnostic Oral

Product Number: 502461

Synonyms: Sodium Iodide I 131 Capsules, Na¹³¹I, ¹³¹I, I-131

Manufactured by:

DRAXIMAGE, a division of Draxis Specialty
Pharmaceuticals Inc.
16751 TransCanada Hwy.
Kirkland, QC, H9H 4J4

Information Tel. No.:

(514) 630-7043

1-888-633-5343

CANUTEC:

(613) 996-6666

Web Site:

www.draximage.com

Category: Therapeutic oral radiopharmaceutical

SECTION 2. COMPOSITION, INFORMATION ON HAZARDOUS INGREDIENTS

Chemical Ingredients:

	<u>CAS No.</u>	<u>%</u>
† Sodium Iodide I 131	7790-26-3	<0.001
Dibasic Sodium Phosphate	7558-79-4	>86
Hard Gelatine Capsule	N/A	<14
Disodium Edetate (EDTA)	6381-92-6	<0.1
Sodium Thiosulfate	10102-17-7	<0.1

- Appearance: Hard gelatine capsules, coloured white and pink, or white and yellow, or white and orange, or white and grey, or white and green.
- The capsule is odourless.

† Radioactive ingredient; between 0.009 and 0.1 mCi (0.33 and 3.70 MBq) per capsule at the time of calibration. High energy gamma emitter. Half-life 8.04 days.

CNSC Permitted Exposures: 50 mSv/yr for radiation workers, 1 mSv/yr for Public
Iodine 131 has a clearance half-life of less than 10 days. The occupational Regulated Limit on Intake (ALI) is 30 µCi (1110 kBq).

Sodium Iodide I 131 Capsule, USP, Diagnostic

SECTION 3. HEALTH HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

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

Do not remove the product from its protective shielding unless by qualified personnel. Promptly remove any contamination from skin or eyes, remove contaminated clothing. Avoid all unnecessary exposure to the chemical substance.

POTENTIAL HEALTH EFFECTS

DRAXIMAGE™ Sodium Iodide I 131 Capsules, USP, Diagnostic contains radioactivity.

Skin Contact:

Significant radiation dose is possible; wash skin immediately on contact.

Inhalation:

Respiration and inhalation of vaporous I 131 can result in a significant thyroid radiation dose. No respiratory symptoms.

Ingestion:

Ingestion of I 131 Solution can result in a significant thyroid radiation dose.

Eye Contact:

Significant radiation dose is possible; wash eyes immediately on contact.

Aggravation of Pre-existing Conditions:

No information found.

CARCINOGENICITY

Compounds containing radioactive I-131 emit ionizing radiation. High doses of ionizing radiation increase the risk of cancer to those who are exposed; however radiological health effects have not been demonstrated for doses of less than 10 rem (100 mSv) delivered at high dose rates.

SECTION 4. FIRST AID MEASURES

Inhalation:

Remove to fresh air, support breathing by usual methods if necessary. Stand upwind if possible. Ascertain if individual has allergies to iodine. If not, administer stable iodine (eg. Lugol's solution). Seek medical attention for radiation intake.

Ingestion:

Wash out mouth with water; call physician if necessary. Ascertain if individual has allergies to iodine. If not, administer stable iodine (eg. Lugol's solution). Seek medical attention for radiation intake.

Skin Exposure:

Wash exposed area with soap and water. Avoid skin abrasion. Remove contaminated clothing. Get medical advice for external radiation exposure or if irritation develops.

Eye Exposure:

Wash open eyes thoroughly with running water for at least 15 minutes. Get medical advice for external radiation exposure or if irritation develops.

IN ALL CASES OBTAIN MEDICAL ASSISTANCE IMMEDIATELY

Sodium Iodide I 131 Capsule, USP, Diagnostic

SECTION 5. FIRE FIGHTING MEASURES

Fire: Presents no combustion hazard. No Flash Point or Autocombustion Temperature.

Explosion: Not considered to be an explosion hazard.

Fire Extinguishing Media: Use a dry chemical extinguisher on small fires, water spray, fog or foam on large fires; do not use a water stream.

Special Instructions: In the event of a fire, the principal hazard will be from volatile I 131. 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

**EVACUATE THE AREA AND CONTROL ACCESS
NOTIFY THE LOCAL RADIATION SAFETY OFFICER**

In the case of a spill or leak of this material, wear protective clothing, a personal respirator, chemical-resistant rubber gloves, chemical safety goggles, and shoe covers. Soak up the solution with vermiculite or charcoal. Monitor the area continuously to prevent the spread of radioactive contamination. Place material in a suitable lead container. 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 and wash the area several times with water rinses. Dispose of all cleaning material and wash water according to the requirements for radioactive material.

SECTION 7. HANDLING AND STORAGE

All shippers and consignees of this material must possess a valid radioisotope licence issued by the appropriate federal or state authority.

The material should be stored at or below room temperature in a tightly-closed shielding container stored in a dry, ventilated area.

Wear protective clothing, including chemical safety goggles and chemical-resistant waterproof gloves. Wash hands and forearms after handling.

Sodium Iodide I 131 Capsule, USP, Diagnostic

SECTION 8. EXPOSURE CONTROLS, PERSONAL PROTECTION

Engineering Controls:

Adequate ventilation to remove volatile I 131 is essential. Use a chemical fume hood for adequate ventilation. A safety shower and eyewash should be available. Keep solution behind lead glass windows whenever possible.

Eye/Face Protection:

Wear safety goggles.

Respiratory Protection:

Use a personal respirator with a combination radionuclide cartridge or a SCBA where a spill has occurred.

Skin Protection:

Wear protective gloves and clean body-covering clothing.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Hard gelatine capsules, coloured white and pink, or white and yellow, or white and orange, or white and grey or white and green.

Odour: Odourless

Solubility: Soluble in water.

Melting Point: N/A

Molecular formula: Active ingredient: Na¹³¹I,
Carrier: Na₂HPO₄

SECTION 10. STABILITY AND REACTIVITY

Stability: Stable under ordinary conditions of use and storage.

Hazardous Decomposition Products:

When heated to decomposition, substance will emit gaseous I 131.

Hazardous Polymerisation: Will not occur.

Incompatibilities with other Materials: Acids will cause the release of gaseous I 131.

SECTION 11. TOXICOLOGICAL INFORMATION

Harmful if ingested. Ingestion of I 131 Solution can result in a significant thyroid radiation dose. For detailed toxicological information on specific components, write to the address listed in Section 1 – Attn: Regulatory Affairs Department.

Sodium Iodide I 131 Capsule, USP, Diagnostic

SECTION 12. ECOLOGICAL INFORMATION

Not available.

SECTION 13. DISPOSAL CONSIDERATIONS

Dispose of all waste material according to the site licence requirements for the disposal of radioactive material or proceed as directed by the local Radiation Safety Officer. Consult local, state, or federal regulations for proper disposal.

SECTION 14. TRANSPORTATION INFORMATION

DOT (Department of Transportation) and **IATA** (International Air Transport Association) regulated.

SECTION 15. REGULATORY INFORMATION

HCS: Class: 7 (Radioactive Material)

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 July 27, 2006
Product Use: Therapeutic Oral Radiopharmaceutical
Revision Information: This is the original version.

DRAXIMAGE 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. DRAXIMAGE, A DIVISION OF DRAXIS SPECIALTY PHARMACEUTICALS INC. 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 TO THE PRODUCT TO WHICH THE INFORMATION REFERS. ACCORDINGLY, DRAXIMAGE Inc. WILL NOT BE RESPONSIBLE FOR DAMAGES RESULTING FROM USE OF OR RELIANCE UPON THIS INFORMATION.