

MATERIAL SAFETY DATA SHEET
Sodium Iodide I 131 Solution, USP



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SECTION 1. CHEMICAL PRODUCT & COMPANY IDENTIFICATION

Product Name: Kit for the Preparation of Sodium Iodide I 131 Capsules, USP
Product Number: 502880

Synonyms: Sodium Iodide I 131 Solution, ¹³¹I, Na¹³¹I, I-131
Category: Therapeutic oral radiopharmaceutical

Manufactured by:
DRAXIMAGE, a division of DRAXIS Specialty Pharmaceuticals Inc.,
A Jubilant Organosys Company
16751 TransCanada Hwy.
Kirkland, QC, H9H 4J4

Information Tel.
(514) 630-7080
1-888-633-5343

CANUTEC: (613) 996-6666
Web Site: www.draximage.com

SECTION 2. COMPOSITION, INFORMATION ON INGREDIENTS

Chemical Ingredients:

	<u>CAS No.</u>	<u>% (wt)</u>
† Sodium Iodide ¹³¹ I	7790-26-3	<0.001
Dibasic Sodium Phosphate	7558-79-4	<4.0
Sodium Thiosulfate	10102-17-7	<0.44
Disodium Edetate (EDTA)	6381-92-6	<0.2

† Highly radioactive ingredient; 1,000 to 2,000 mCi/mL. High energy gamma emitter. Half-life 8.02 days.

Canadian Nuclear Safety Commission Permitted Exposures: 50 mSv/yr for radiation workers, 1 mSv/yr for the general Public.

Iodine 131 has a clearance half-life of less than 10 days. The CNSC Annual Limit on Intake (ALI) for Iodine 131 is 9.1E+05 Bq (approx. 25 µCi) by ingestion and 1.0E+06 Bq (approx. 27 µCi) by inhalation. The US Nuclear Regulatory Commission ALI is 30 µCi by ingestion and 50 µCi by inhalation.

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SECTION 3. 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 vial from its protective lead 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 Solution is a highly radioactive solution.

Skin Contact:

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

Inhalation:

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

Ingestion:

Ingestion of ¹³¹I 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 ¹³¹I emit ionizing radiation. High doses of ionizing radiation can increase the risk of cancer to those who are exposed; however radiogenic 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

First responders: the following actions, including remediation, should be carried out by qualified individuals. In cases where life threatening injury has resulted, **first** treat the injury, **second** deal with personal decontamination.

IN ALL CASES OBTAIN MEDICAL ASSISTANCE IMMEDIATELY

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.

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SECTION 5. FIRE FIGHTING MEASURES

Fire: Presents no combustion hazard. No flash point or auto combustion 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 ^{131}I . Wear full protective clothing and NIOSH-approved self-contained breathing apparatus with full face piece 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 shielded container stored in a dry, ventilated area.

Use handling equipment such as tongs and reduce handling times to a minimum in order to reduce personal radiation exposure.

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

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SECTION 8. EXPOSURE CONTROLS, PERSONAL PROTECTION

Engineering Controls:

Once the product is removed from its sealed container, adequate ventilation to remove volatile ^{131}I 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.

Respiratory Protection:

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

Eye/Face Protection:

Wear safety goggles.

Skin Protection:

Wear protective gloves and clean body-covering clothing.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Clear, colorless water-like solution in a sealed 3 cc V-bottom glass vial. **Melting Point:** N/A

Odour: Odourless

pH: 7.5 to 9.0

Solubility: Soluble in water.

Molecular formula: Na^{131}I

Radioactivity: Up to 500 mCi and 1000 mCi ^{131}I (18.5 to 37 GBq)

Radioactive Concentration: Up to 2000 mCi/mL (74 GBq/mL)

SECTION 10. STABILITY AND REACTIVITY

Stability: Stable under ordinary conditions of use and storage.

Hazardous Polymerisation: Will not occur.

Hazardous Decomposition Products: When heated to decomposition, substance will emit gaseous ^{131}I .

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

SECTION 11. TOXICOLOGICAL INFORMATION

Harmful if ingested. Ingestion of ^{131}I 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.

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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.

NFPA Ratings: Health: 1 Flammability: 0 Reactivity: 0

SECTION 16. OTHER INFORMATION

MSDS Status: Revised February 2, 2010
Product Use: Therapeutic Oral Radiopharmaceutical
Revision Information: Rev. 2. Periodic review with minor updates in format and content.

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