



Safety Data Sheet

1. IDENTIFICATION

Product Name: DRAXIMAGE® Sodium Iodide I 131 Capsules USP, Therapeutic
DRAXIMAGE® Sodium Iodide I 131 Capsules USP, Diagnostic

Product Number: 502440 Therapeutic
502460/502461 Diagnostic

Recommended use: Therapeutic or diagnostic oral radiopharmaceutical imaging agent

Restrictions for use: Must be handled by persons qualified to handle radioactive materials.

Manufacturer: Jubilant DraxImage Inc.
16751 TransCanada Highway
Kirkland, Quebec, Canada, H9H 4J4
Phone: +1-514-630-7080 / 1-888-633-5343
Fax: +1-514-694-9295 / 1-866-431-4288
Hours of operation: 8am-5pm Eastern Time
Web site: <http://www.draximage.com>

Emergency Phone: CANUTEC: +1-613-996-6666

Synonyms and Trade names: Sodium Iodide I-131 Solution, Na¹³¹I, ¹³¹I, I-131

Category: Therapeutic or diagnostic oral radiopharmaceutical imaging agent

2. HAZARD IDENTIFICATION

Classification: Radiological Hazard

Health Hazards: DRAXIMAGE® Sodium Iodide I 131 Capsule, USP, contains radioactivity.

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

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.

Aggravation of Pre-existing Conditions: No information found.

Precautions:

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

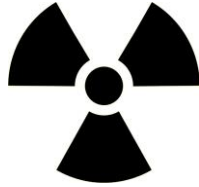
Do not remove the product from its protective shielding unless by qualified personnel. Consult with your facility's Radiation Safety Officer for adequate procedures specific to the radionuclide and quantity before handling this radioactive product. Promptly remove any contamination from skin or eyes, remove contaminated clothing and notify your radiation safety personnel immediately. Avoid all unnecessary exposure to the chemical substance.

Compounds containing I-131 can become volatile, especially when heated. Use adequate ventilation, waterproof gloves, lab coat, and local radioactivity monitoring instruments.

Does not present other hazards within the WHMIS/GHS list of Physical Hazard Classes.

Label Elements:

Signal Word: Caution Radioactive Material
Rayonnement Danger Radiation
Symbol: Basic ionizing radiation symbol



3. COMPOSITION/INFORMATION ON INGREDIENTS

Ingredients	CAS #	Wt %
Sodium Iodide I 131 †	7790-26-3	< 0.001 %
Dibasic Sodium Phosphate	7558-79-4	> 84 %
Hard Gelatine Capsule	N/A	<16 %
Sodium Thiosulfate	10102-17-7	< 1 %
Disodium Edetate (EDTA)	6381-92-6	< 0.1 %

† Radioactive ingredient; between 111 MBq and 7,400 MBq (3 mCi to 200 mCi) per therapeutic capsule and 3.7 MBq (100 µCi) per diagnostic capsule at the time of calibration. High energy gamma emitter. Half-life 8.04 days. Appearance: hard gelatine capsules, coloured white (therapeutic) or white and pink, or white and yellow, or white and orange, or white and grey, or white and green (diagnostic).

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

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.

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 (e.g. 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 (e.g. Lugol’s solution). Seek medical attention for radiation intake.

5. FIRE-FIGHTING MEASURES

Fire: Presents no combustion hazard. No flash point or auto combustion temperature.

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 to avoid the potential to spread radioactivity.

Fire Fighting: Keep personnel removed and upwind from fire. Wear self-contained breathing apparatus. Wear full protective equipment.

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 face piece operated in the pressure demand or other positive pressure mode.

6. ACCIDENTAL RELEASE MEASURES

**ALERT EVERYONE IN THE AREA,
EVACUATE THE AREA AND CONTROL ACCESS
NOTIFY THE LOCAL RADIATION SAFETY OFFICER, ASK FOR ASSISTANCE**

All cleanup operations should be performed according to the Standard Operating Procedures (SOP) for radiation protection established for your facility and by the CNSC, NRC, or other applicable local, provincial, state or federal regulations.

In the case of a spill or leak of this material, minimize exposure times, wear protective clothing, a personal respirator, chemical-resistant rubber gloves, chemical safety goggles, and shoe covers. Soak up any liquid with an absorbent pad. Monitor the area continuously to prevent the spread of radioactive contamination. Place cleanup materials in a suitable lead container. If on site, follow the site licence requirements for the disposal of cleanup materials as radioactive material or proceed as directed by the local Radiation Safety Officer. Ventilate and wash the area several times with water rinses – do not use acidic solutions. Dispose of all cleaning material and wash water according to the requirements for radioactive material.

7. HANDLING AND STORAGE

Minimize handling times.

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. Do not freeze.

Avoid contact with skin. 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.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure to this radioactive material should be controlled according to all Federal, State and local regulations for the use of radioactive materials. Specific Standard Operating Procedures (SOPs) to prevent undue exposure to radioactive materials should be in place and those using this material should be training in those procedures.

Occupational Exposure Limit: The Canadian Nuclear Safety Commission Permitted Exposures are 50 mSv/yr for radiation workers and 1 mSv/yr for the general Public.

The committed effective dose per unit intake for I-131 is 2.2E-08 Sv/Bq by ingestion and 1.1 E-08 Sv/Bq by inhalation. Reference: Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, IAEA Safety Standards Series No. GSR Part 3, International Atomic Energy Agency, Vienna, 2014, p. 168.

Iodine-131 has a clearance half-life of less than 10 days.

Skin Protection: Wear protective gloves and clean body-covering clothing.

Eye/Face Protection: Wear safety goggles.

Engineering Controls: Once the product is removed from its sealed container, 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.

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

9. PHYSICAL AND CHEMICAL PROPERTIES

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

Odour: Odourless

Odour Threshold: Not applicable

pH: Not applicable
Solubility: Soluble in water
Melting point: Not applicable
Freezing point: Not applicable
Initial Boiling point and boiling range: Not applicable
Flash Point: Not applicable
Evaporation rate: Not applicable
Flammability: Not applicable
Vapour pressure: Not applicable
Vapour density: Not applicable
Relative density: Not applicable
Partition coefficient: Not applicable
Auto-ignition temperature: Not applicable
Decomposition temperature: Not applicable
Viscosity: Not applicable
Physical Half-life (¹³¹I): 8.04 days

10. Stability and Reactivity

Reactivity: Low
Chemical Stability: Stable under recommended conditions of use and storage.
Possibility of Hazardous Reactions: None reasonably foreseeable
Conditions to Avoid: None under recommended conditions of use and storage.
Incompatible Materials: Acids will cause the release of gaseous I-131.
Hazardous Decomposition Products: When heated gaseous I-131 may be emitted.

11. Toxicological Information

Harmful if ingested. Ingestion of I 131 Solution can result in a significant thyroid radiation dose. Other routes of absorption of I-131 causing internal radiation doses include inhalation of gaseous I-131 and absorption through skin or eye contact.
Symptoms of I-131 ingestion or absorption will not likely present in the short term.
None of the non-radioactive components of the product mixture are present above the concentration limit designated for its hazard class. For detailed toxicological information on specific components, write to the address listed in Section 1 – Attn: Regulatory Affairs Department.
Carcinogenicity: Compounds containing radioactive I-131 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.

12. Ecological Information

After an established decay period based on the physical half life of I-131, the material can be disposed according to Federal, Provincial, State and local regulations for the disposal of decayed radioactive material.
Ecotoxicity: Not available

13. Disposal Considerations

Radioactive waste must be handled in accordance with procedures established by your Radiation Safety Officer, NRC, CNSC, 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.

14. Transportation Information

DOT (Department of Transportation Regulations): Regulated as radioactive material, class 7.
IATA (International Air Transport Association): Described as radioactive material, class 7.

15. Regulatory Information

This Safety Data Sheet (SDS) has been prepared according to current WHMIS requirements for SDS in Part 4 of the Hazardous Products Regulations (HPR) and contains all of the information required by the regulation.

NFPA Ratings:

Health: 1

Flammability: 0

Reactivity: 0

16. Other Information

Revision Information: Revision 4, January 5, 2017

For additional information on I-131, refer to the Canadian Nuclear Safety Commission Radiation Radionuclide Information Booklet at http://www.nuclearsafety.gc.ca/pubs_catalogue/uploads/Radionuclide-Information-Booklet-2016-eng.pdf.

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