MATERIAL SAFETY DATA SHEET

DRAXIMAGE® Sodium Iodide I 131 Capsule, USP

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Section 1: Product and Company Identification

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

Manufacturer:
Jubilant DraxImage Inc.
A Jubilant Life Sciences Company
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Hours of operation: 8am-5pm Eastern Time
Web site: www.draximage.com

Synonyms and Trade names: Sodium Iodide I-131 Capsules, $Na^{131}I$, ^{131}I, I-131

Category: Therapeutic or diagnostic radiopharmaceutical imaging agent

Product Number: 502440/502441 Therapeutic
502460/502461 Diagnostic

Section 2: 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 Capsule, USP, Diagnostic 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.

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 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 %

- 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 or white and blue (diagnostic).

- The capsule is odourless.

† Radioactive ingredient; between 111 MBq and 7,400 MBq (3 to 200 mCi) per therapeutic capsule and between 0.33 MBq and 37 MBq (9 to 100 μCi) per diagnostic capsule at the time of calibration.

High energy gamma emitter. Half-life 8.04 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 E+05 Bq (approximately 24 μCi) by ingestion and 2 E+06 Bq (approximately 54 μCi) by inhalation. The US Nuclear Regulatory Commission ALI is 30 μCi by ingestion and 50 μCi by inhalation.

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

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.

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.

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.

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.

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.

Section 6: Accidental Release Measures

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

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 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 – do not use acidic solutions. Dispose of all cleaning material and wash water according to the requirements for radioactive material.

Section 7: Handling and Storage

Minimize handling times.

All shippers and consignees of this material must possess a valid radioisotope license 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.

Section 8: Exposure Controls / Personal Protection

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

Eye/Face Protection: Wear safety goggles.

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.

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

Section 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 or white and blue.

Odour: Odourless.

Solubility: Soluble in water.

Melting Point: N/A

Molecular formula: Active ingredient: $Na^{131}I$, Carrier: Na_2HPO_4

Physical Half-life (^{131}I): 8.04 days

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.

Section 12: Ecological Information

Ecotoxicity: Not available.

BOD5 and COD: Not available.

Products of Biodegradation: Not available.

Toxicity of the Products of Biodegradation: No information available.

Special Remarks on the Products of Biodegradation: No information available.

Section 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.

Section 14: Transportation Information

DOT (Department of Transportation Regulations): Regulated as radioactive material, class 7.

IATA (International Air Transport Association): Regulated as radioactive material, class 7.

Section 15: Regulatory Information

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

Product Use: Therapeutic or diagnostic oral radiopharmaceutical
MSDS Status: Published in July 2006
Revision Information: Rev. 3, July 2011

For additional information, refer to the Canadian Nuclear Safety Commission Web site at http://www.nuclearsafety.gc.ca/eng/readingroom/radiationsafety/index.cfm
and/or the United States Nuclear Regulatory Commission Web site at
http://www.nrc.gov/materials/src-materials-facilities/regs-guides-comm.html

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