



Safety Data Sheet

1. IDENTIFICATION

Product Name: RUBY-FILL® Rubidium Rb 82 Generator
Product Number: 502125, 8300000021
Recommended use: Diagnostic injectable radiopharmaceutical generator; active agent produced by generator is Rubidium-82 Chloride Injection.
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: Rubidium-82 Generator, Strontium-82/Rubidium-82 generator, ⁸²Rb, Rb-82
Category: Diagnostic injectable radiopharmaceutical generator

2. HAZARD IDENTIFICATION

Classification: Radiological Hazard

Health Hazards: **DRAXIMAGE® Rubidium Rb 82 Generator contains radioactivity.**

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

Skin Contact: Significant radiation dose is possible; wear protective waterproof gloves and wash skin immediately on contact.

Inhalation: Under normal circumstances, this product is not volatile and does not present a danger for inhalation. No respiratory symptoms

Ingestion: Ingestion of large quantities of this material is not expected to occur. Ingestion of trace amounts due to contamination of hands may lead to an internal 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**

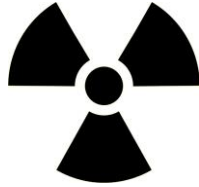
Do not remove the product from its protective shielding unless by qualified personnel. Consult with your facility's Radiation Safety Officer for adequate procedures specific to the radionuclide and quantity before handling this radioactive product. Promptly remove any contamination from skin or eyes,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

Compounds containing radioactive Sr-82, Sr-85 or Rb-82 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 100 mSv (10 rem) delivered at high dose rates.

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 % |
|---------------------------------|--|------|
| Strontium Sr-82/Sr-85 Chloride† | 7440-24-6* | N/A |
| Rubidium-82 Chloride | | N/A |
| Normal saline 0.9% | 7647-14-5 (NaCl) 7732-18-5 (H ₂ O) | |
| Stannic Oxide (Tin oxide) | 18282-10-2 | NA |

† Radioactive ingredient; between 3145 and 4255 MBq (85 and 115 mCi) per generator at the time of calibration; decreasing with time due to physical radioactive decay. Half-life of Sr-82 is 25.6 days and of Sr-85 is 64.9 days. Rb-82 is a high-energy positron emitter with a half-life of 76 seconds.

* CAS number is for non-radioactive strontium.

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. Seek medical attention for radiation intake.

Ingestion: Wash out mouth with water; call physician if necessary. Seek medical attention for radiation intake.

5. FIRE-FIGHTING MEASURES

Fire: Presents no combustion hazard. No flash point or auto combustion temperature is available for tin oxide.

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.

Explosion: Not considered to be an explosion hazard.

Special Instructions: In the event of a fire, the principal hazard will be from volatile or particulate radioactivity. 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 of the Rb 82 generator eluate, any skin contamination or contaminated materials that are close to a person should be removed as quickly as possible in order to reduce the risk of high skin doses from this high-energy beta source, however because of the relatively short half-life of Rb-82 consideration should be given to moving away from the site of the spill and delaying the area cleanup for approximately 15-30 minutes to allow the Rb-82 to decay to acceptable levels. After decay of Rb-82, cleanup should be done wearing impermeable gloves in case there are traces of Sr-82 that remain. If cleanup is necessary before the Rb-82 decay is complete, the local Radiation Safety Officer should be consulted for additional personal protection measures, which could include the use of shielding and remote manipulators.

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. 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: Canadian Nuclear Safety Commission Permitted Radiation Exposures: 50 mSv/yr for radiation workers, 1 mSv/yr for the general Public. The committed effective dose per unit intake for Sr-82 is 6.1E-09 Sv/Bq by ingestion and for Sr-85 is 5.6 E-10 Sv/Bq by ingestion. 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. 233.

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

Eye/Face Protection: Wear safety goggles.

Engineering Controls: Provide adequate room ventilation. A safety shower and eyewash should be available.

Respiratory Protection: No special protection is anticipated in normal clinical use. Unusual exposure conditions may require the use of a personal respirator with a combination radionuclide cartridge or a SCBA.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: a shielded stainless steel column containing a slurry of normal saline and stannic oxide onto which Strontium-82/Strontium-85 has been adsorbed. The product of the generator is a clear, colorless solution that should be adequately shielded at all times.

Molecular formula: Active ingredient: $^{82}\text{SrCl}$ and $^{82}\text{RbCl}$
Carrier: SnO_2 and NaCl

Odour: Odourless

Odour Threshold: Not applicable

pH: above 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: of Sr-82 is 25.6 days and of Sr-85 is 64.9 days. Rb-82 is a high-energy positron emitter with a half-life of 76 seconds.

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: None

Hazardous Decomposition Products: When heated to decomposition, substance will emit particulate ⁸²Sr, ⁸⁵Sr and ⁸²Rb.

11. Toxicological Information

Not applicable. For detailed toxicological information on specific components, write to the address listed in Section 1 – Attn: Regulatory Affairs Department.

Carcinogenicity: Compounds containing radioactive ⁸²Sr, ⁸⁵Sr or ⁸²Rb 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

Ecotoxicity: Not available

13. Disposal Considerations

Waste disposal: 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.

16. Other Information

Revision Information: Revision 2, January 24, 2017

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