SAFETY DATA SHEET

DRAXIMAGE® Rubidium Rb 82 Generator

1. Identification

Product identifier:	**DRAXIMAGE® Rubidium Rb 82 Generator**
Other means of identification:	Rubidium-82 Generator, Strontium-82/Rubidium-82 generator, ^{82}Rb, Rb-82
Product number:	502125, 8300000021, 8300000060, 8300000080
Recommended use:	Diagnostic injectable radiopharmaceutical generator; active agent produced by generator is Rubidium-82 Chloride Injection.
Restrictions on use:	Must be handled by persons qualified to handle radioactive materials.
Initial supplier identifier:	Jubilant DraxImage Inc., dba Jubilant Radiopharma 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: www.draximage.com
Emergency telephone number (hours of operation):	1-888-633-5343 (Monday to Friday 8:00 to 17:00)

2. Hazard Identification

This is not a hazardous product under WHMIS 2015 (Hazardous Products Regulations). This product is also not subject to the Global Harmonized System GHS classification.

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.

Outer label elements:

Signal word:	Caution – Radioactive Material Attention – Produit radioactif
Symbol:	Radiation warning symbol

3. Composition/Information on ingredients

Substance or mixture: Mixture

Ingredient	CAS number	Concentration
Strontium Sr-82/Sr-85 Chloride †	7440-24-6*	N/A
Rubidium-82 Chloride	N/A	N/A
Normal saline 0.9%	7647-14-5 (NaCl) 7732-18-5 (H_2O)	N/A
Stannic Oxide (Tin oxide)	18282-10-2	N/A

† Radioactive ingredient; between 3330 and 4255 MBq (90 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.

Within the current knowledge of the supplier and in the applicable concentration, no additional ingredient present is classified as hazardous to health or the environment and therefore do not identification in this 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

Description of necessary first-aid measures

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.

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

Eye contact: Wash immediately with running water for at least 15 minutes. Get medical advice for external radiation exposure or if irritation develops.

Most important symptoms and effects, whether acute or delayed

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.

Skin contact: Significant radiation dose is possible.

Eye contact: Significant radiation dose is possible.

5. Fire-fighting measures

Suitable extinguishing media: This product is not combustible. Use a dry chemical extinguisher on small fires, water spray, fog or foam on large fires.

Unsuitable extinguishing media: Do not use a water stream to avoid the potential to spread radioactivity.

Specific hazards arising from the hazardous product:	In the event of a fire, the principal hazard will be from volatile or particulate radioactivity.
Hazardous combustion products:	When heated to decomposition, substance will emit particulate ^{82}Sr, ^{85}Sr and ^{82}Rb.
Special protective equipment and precautions for fire-fighters:	Keep personnel removed and upwind from fire. Wear NIOSH approved self-contained breathing apparatus with full face piece operated in the pressure demand or other positive pressure mode and full protective clothing.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

For non-emergency personnel:	Evacuate and restrict access to area until completion of cleanup.
For emergency responders:	**ALERT EVERYONE IN THE AREA, EVACUATE THE AREA AND CONTROL ACCESS. NOTIFY THE LOCAL RADIATION SAFETY OFFICER, ASK FOR ASSISTANCE.**

Methods and materials for containment and cleaning up

Accidental release:

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

Precautions for safe handling:	Minimize handling times. Avoid contact with skin. Wear protective clothing, including chemical safety goggles and chemical-resistant waterproof gloves. Wash hands and forearms after handling. All shippers and consignees of this material must possess a valid radioisotope licence issued by the appropriate federal or state authority.
Conditions for safe storage, including any incompatibilities:	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.

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.

Control parameters:	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 5.6E-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.
Appropriate engineering controls:	Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. A safety shower and eyewash should be available.

Individual protection measures

Hand protection:	Wear protective gloves.
Eye protection:	Wear safety glasses with side shields.
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.
Skin and body protection:	Wear clean body-covering clothing.

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}SrCl and ^{82}RbCl Carrier: SnO_2 and NaCl
Odour:	Odourless
Odour threshold:	Not applicable
pH:	Not applicable
Melting point:	Not applicable
Freezing point:	Not applicable
Initial boiling point and boiling range:	Not applicable
Flash point:	Not applicable
Evaporation rate:	Not applicable
Upper and lower flammability or explosive limits:	Not applicable
Vapour pressure:	Not applicable
Vapour density:	Not applicable
Relative density:	Not applicable
Solubility:	Not applicable
Partition coefficient — n-octanol/water:	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:	Not applicable.
Chemical stability:	Under recommended conditions of use and storage, the product is stable.
Possibility of hazardous reactions:	Under normal conditions of use and storage, hazardous reactions will not occur
Conditions to avoid:	None under recommended conditions of use and storage
Incompatible materials:	None reasonably foreseeable.

Hazardous decomposition products:	When heated to decomposition, substance will emit particulate ^{82}Sr, ^{85}Sr and ^{82}Rb.

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 ^{82}Sr, ^{85}Sr or ^{82}Rb 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

Disposal methods:	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. Consult local, provincial, state, or federal regulations for proper disposal.

14.Transport information

International Air Transport Association (IATA/ICAO): Radioactive Material, Class 7.
Department of Transportation Regulations (DOT): Radioactive Material, Class 7.

15.Regulatory information

WHMIS: This Safety Data Sheet (SDS) has been prepared according to the Workplace Hazardous Materials Information Systems (2015) requirements of the Hazardous Products Regulations (HPR) and the SDS contains all of the information required by the HPR.

16.Other information

SDS information

Version:	4
Date (dd/mm/yyyy):	06/11/2020
Prepared by:	CFT Canada

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