

# Safety Data Sheet

acc. to OSHA HCS

Printing date 10/02/2015

Version 2

Reviewed on 10/02/2015

## 1 Identification

### **Product identifier**

**Sheet Code:** 279

**Trade name:** CardioGen-82

**Chemical Name:** Rubidium Rb-82 generator for elution of rubidium chloride Rb-82 injection.

**Synonyms:** For active: Rubidium Chloride 82, Rubidium Chloride Rb-82 Injection.

### **How Supplied:**

Rubidium Rb-82 generator supplied in the form of strontium Sr-82 adsorbed on a hydrous stannic oxide column which is encased in a lead shield and surrounded by a plastic container.

### **Relevant identified uses of the substance or mixture and uses advised against**

We recommend that you use this product in a manner consistent with the listed use. If your intended use is not consistent with the stated use, please contact your sales or technical service representative.

### **Application of the substance / the mixture:**

A myocardial perfusion agent useful in distinguishing normal from abnormal myocardium.

**Chemical Family:** Radioisotope of rubidium.

**Molecular Formula:** For active,  $^{82}\text{RbCl}$  (radioisotope).

**CAS Number:** 7791-11-9 (pertains to rubidium chloride).

### **Details of the supplier of the safety data sheet**

#### **Manufacturer/Supplier:**

Bracco Diagnostics Inc.  
P.O. Box 5225  
Princeton, NJ 08543

#### **Further Information Obtainable from:**

B-Lands Consulting  
WTC, 5 Place Robert Schuman, BP 1516  
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#### **Information department:**

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#### **Emergency telephone number:**

EMERGENCY CONTACT:  
Health: 1-800-257-5181  
U.S. Transport - Chemtrec: 1-800-424-9300  
International Transport - Chemtrec: 1-703-527-3887

#### **Emergency Overview:**

The CardioGen-82 Rubidium Rb 82 Generator is a shielded column that contains a slurry of normal saline solution and stannic oxide to which Strontium Sr-82/Sr-85 has been adsorbed.

As in the use of any radioactive material, care should be taken to insure minimum radiation exposure.

Personnel who handle radioactive materials should be trained in their use and should follow appropriate precautions for work with these materials.

See specifications for radioactivity on package.

See Health Effects and Toxicology sections for additional information.

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Not applicable

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## 2 Hazard(s) identification

### Classification of the substance or mixture

The product is not classified according to the Globally Harmonized System (GHS).

### Label elements

**GHS label elements** Not applicable.

**Hazard pictograms** Not applicable.

**Signal word** Not applicable.

**Hazard statements** Not applicable.

### Effects of Overexposure - Routes of Entry:

#### Inhalation:

Under normal conditions, this material is adsorbed on a hydrous stannic oxide column, which is then encased in a lead shield and surrounded by a plastic container. Exposure by inhalation is not expected to occur.

**Skin Contact:** Exposure may occur via skin contact if gloves and protective clothing are not worn.

#### Ingestion:

Ingestion of large quantities of this material in an occupational setting would not be expected to occur.

Ingestion of trace amounts of the material might occur if the material contacts hands and hands are not washed prior to eating, drinking or smoking.

### Additional Information:

#### Information pertaining to particular dangers for man and environment:

Negative Effects on the Health: See also Sections 11

Negative Effects on the Environment: See also Section 12

#### NFPA ratings (scale 0 - 4)



Health = 0

Fire = 0

Reactivity = 0

#### HMIS-ratings (scale 0 - 4)



HEALTH 0 Health = 0

FIRE 0 Fire = 0

REACTIVITY 0 Reactivity = 0

#### Results of PBT and vPvB assessment

**PBT:** Not applicable.

**vPvB:** Not applicable.

## 3 Composition/information on ingredients

### Chemical characterization: Substances

#### Impurities and stabilising additives:

CAS: 1310-73-2 EINECS: 215-185-5 Index number: 011-002-00-6	Sodium Hydroxide	⚠ Skin Corr. 1A, H314
EINECS: 231-595-7 Index number: 017-002-01-X RTECS: MW 9620000	hydrochloric acid	⚠ Skin Corr. 1B, H314; ⚠ STOT SE 3, H335

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**Chemical characterization: Mixtures**

**Description:** Mixture: consisting of the following components.

**Hazardous Components:**

CAS: 18282-10-5 EINECS: 242-159-0 RTECS: XQ 4000000	TIN (IV) OXIDE	NA%
CAS: 1310-73-2 EINECS: 215-185-5 Index number: 011-002-00-6	Sodium Hydroxide ⚠ Skin Corr. 1A, H314	<1%
CAS: 7440-24-6 EINECS: 231-133-4	Strontium <sup>82</sup> /Strontium <sup>85</sup> (**) ⚠ Water-react. 1, H260	NA%
EINECS: 231-595-7 Index number: 017-002-01-X RTECS: MW 9620000	hydrochloric acid ⚠ Skin Corr. 1B, H314; ⚠ STOT SE 3, H335	<1%

**Additional information:**

\*\* CAS number pertains to Strontium

When sterile, pyrogen-free Sodium Chloride Injection USP is used to elute the generator, the diagnostic agent Rubidium Chloride Rb-82 injection is formed. The resulting material is radioactive.

Rubidium Rb-82 (eluent from CardioGen-82 generator) decays by positron emission and associated gamma emission with a physical half-life of 75 seconds. The specific gamma ray constant for Rb-82 is 6.1 R /h-mCi at 1 cm. The first half-value layer is 0.7 cm of lead (Pb).

For the wording of the listed risk phrases refer to section 16.

## 4 First-aid measures

**Description of first aid measures**

**General information:**

Formulation contains RADIOACTIVE CHROMIUM 51.

As in the use of any radioactive material, care should be taken to insure minimum radiation exposure. Personnel who handle radioactive materials should be trained in their use and should follow appropriate precautions for work with these materials. See Health Effects and Toxicology sections for additional information.

**After Inhalation:** Supply fresh air. If required, provide artificial respiration.

**After Skin Contact:**

Remove contaminated clothing.

Wash with water and rinse thoroughly for 5 minutes.

Seek medical attention if irritation (redness, itching or swelling) develops or persists.

Swab skin to verify all removable radioactive contamination is gone.

**After Eye Contact:**

Wash with running water for several minutes holding the eyelids open.

If any symptoms of irritation develop and / or persist, consult your doctor.

Swab eyelid and surrounding area to verify all removable radioactive contamination is gone.

**After Swallowing:**

Get medical attention immediately.

Vomiting may be induced only if a person is conscious and if ingestion has occurred within the past three hours.

Never induce vomiting in a person who is unconscious or experiencing convulsions.

If ingestion of eluent from the CardioGen-82 generator (containing radioactive Rubidium-82) inadvertently occurs, the individual may be treated by water hydration or diuresis to facilitate elimination of the radioactive material.

**Most important symptoms and effects, both acute and delayed** See also Section 2 and 11.

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**Indication of any immediate medical attention and special treatment needed**

No further relevant information available.

**Means of Specific and Immediate Treatment to Keep at the Workplace:** No special measures required.

**Note to physicians:** None.

## \* 5 Fire-fighting measures

**Extinguishing media**

**Suitable extinguishing agents:** In case of fire, flood with Water

**For safety reasons unsuitable extinguishing agents:** Unknown.

**Special hazards arising from the substance or mixture** See also Section 10.

**Additional Information:** WARNING: Material is RADIOACTIVE

**Advice for Firefighters**

Evacuate personnel to an upwind direction, remove unneeded material and cool container(s) with water from a maximum distance.

Move container from fire area if you can do it without risk.

**Protective Equipment:**

Firefighters should wear adequate personal protective equipment with protection of respiratory tract (self-contained breathing apparatus) (SCBA).

Wear flame and chemicals resistant clothing, boots and gloves (see Section 8).

## \* 6 Accidental release measures

**Personal precautions, protective equipment and emergency procedures**

Wear protective equipment appropriate to the circumstances (see Section 8)

Radioactive shielding if appropriate to minimize exposure

**Environmental precautions:**

Do not allow product to reach sewage system, any water course or penetrate the ground/soil.

Inform respective authorities in case of seepage into water course, sewage system or into the ground.

**Methods and material for containment and cleaning up:**

Absorb with liquid-binding material (sand, diatomite, vermiculite) or other non combustible absorbent material.

Place spilt material in an appropriate container for disposal.

The spill area should be ventilated and decontaminated after material is collected.

Dispose of radioactive material in accordance with all local, state, federal and EC Regulations or with the Regulations of the country in which the material is used.

**Reference to other sections**

See Section 7 for information on Safe Handling.

See Section 8 for information on Personal Protection Equipment.

See Section 13 for Disposal Information.

See Section 12 for Ecological Information.

## \* 7 Handling and storage

**Precautions for Safe Handling** Avoid skin and eye contact.

**Handling:**

Radioactive materials may pose significant health risks if not properly handled. Personnel who handle radioactive materials should be trained in their use and should follow appropriate precautions for work with these materials.

Radiopharmaceuticals should be used only by physicians who are qualified by training and experience in the safe use and handling of radionuclides) and whose experience and training have been approved by the

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appropriate government agency authorized to license the use of radionuclides.

**Conditions for Safe Storage, including any Incompatibilities**

**Requirements to be met by Storerooms and Receptacles:**

Store in a cool, dry place in tightly closed receptacles.

**Container Requirements:**

The CardioGen-82 (Rubidium Rb 82 Generator) is encased in a lead shield surrounded by a labeled plastic container.

**Storage Conditions:** Store at 20-25 degrees C.

**Information about Storage in one Common Storage Facility:** Not required.

**Further information about storage conditions:** None.

**Specific end use(s)** No further relevant information available.

### 8 Exposure controls/personal protection

**Additional information about design of technical systems:** No further data; see item 7.

**Control parameters**

**Components with limit values that require monitoring at the workplace:**

**18282-10-5 TIN (IV) OXIDE**

IOELV (EU)	Long-term value: 2 mg/m <sup>3</sup> as Sn
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**1310-73-2 Sodium Hydroxide**

TLV-ACGIH (USA)	Long-term value: 2 mg/m <sup>3</sup> absolute limit value for 2009
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**Additional information:**

The lists that were valid during the creation were used as basis.

The Exposure Limit for Stannic Oxide as Tin, is 2 mg / m<sup>3</sup> for the OSHA Permissible Exposure Limit (PEL) and for the American Conference of Governmental

Hygienists (ACGIH) Threshold Limit Value-Time Weighted Average (TLV-TWA).

The Occupational Guideline to Exposure to Radioactive Materials is an effective dose equivalent to 50 mSV per year.

**Exposure controls**

**Appropriate Technical Controls:**

Provide adequate aspiration / ventilation in the workplace

Radioactive shielding if appropriate to minimize exposure

**Additional information about Design of Technical Facilities:** No further data (see Section 7).

**Personal protective equipment**

**General Protective and Hygienic Measures:**

The usual precautionary measures for handling chemicals should be followed.

Wash hands before breaks and at the end of work.

Wear protective equipment (PPE) appropriate to the circumstances.



Do not eat, drink, smoke while working.

**Breathing Equipment:**

Not anticipated for normal clinical environment.

In non-routine exposure conditions, where risk assessment shows air-purifying respirators are appropriate, use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Self-contained breathing apparatus should be available for emergency use.

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**Protection of Hands:**



Wear impervious gloves if the potential exists for dermal contact.

**Material of Gloves:**

Latex, Latex / Nitrile or Nitrile Gloves.

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation.

The glove material has to be impermeable and resistant to the product/ the substance/ the mixture.

**Penetration Time of Glove Material:**

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

**Eye Protection:**



Wear safety glasses (ANSI Z87.1)

In the event of a spill, wear chemical safety goggles.

**Body Protection:**

If the risk assessment deems it necessary, wear protective coveralls to prevent contact with the body, due to the splashing and spraying of liquid.

**Limitation and Supervision of Exposure into the Environment:** See also Section 7.

**Additional Information about Design of Technical Systems:** No further data; see Section 7.

### \* 9 Physical and chemical properties

**Information on basic physical and chemical properties**

**General Information**

**Appearance:**

**Form:** Solid

**Odour threshold:** Not determined.

**pH-value:** Not applicable.

**Flash point:** Not applicable.

**Flammability (solid, gaseous):** Not determined.

**Ignition temperature:**

**Decomposition temperature:** Not determined.

**Auto igniting:** Product is not selfigniting.

**Danger of explosion:** Product does not present an explosion hazard.

**Density:** Not determined.

**Relative density** Not determined.

**Vapour density** Not applicable.

**Solubility in / Miscibility with**

**Water:** Insoluble.

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**Partition coefficient (n-octanol/water):** Not determined.

**Viscosity:**

**Dynamic:** Not applicable.

**Kinematic:** Not applicable.

**Other information** No further relevant information available.

## 10 Stability and reactivity

**Reactivity:** There are not particular dangerous reactions with other substances in normal conditions of use.

**Chemical stability:**

This generator contains strontium Sr-82 and Sr-85. Sr-82 decays with a half-life of 25 days and Sr-85 with a half-life of 65 days.

Rubidium Rb-82 (eluent from CardioGen-82 generator) decays by positron emission and associated gamma emission with a physical half-life of 75 seconds. The specific gamma ray constant for Rb-82 is 6.1 R/h-mCi at 1 cm. The first half-value layer is 0.7 cm of lead (Pb).

**Possibility of hazardous reactions:** No dangerous reactions known.

**Conditions to avoid:** No further relevant information available.

**Incompatible materials:** No further relevant information available.

**Hazardous decomposition products:** No further relevant information available ( See Section 5)

## 11 Toxicological information

**Information on toxicological effects**

**Acute toxicity:**

**Toxicological Information for Active Ingredients:**

**LD/LC50 values that are relevant for classification:**

**18282-10-5 TIN (IV) OXIDE**

Oral	LD50	> 20000 mg/kg (Rat)
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**7647-14-5 sodium chloride**

Oral	LD50	3000 mg/kg (Rat)
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**1310-73-2 Sodium Hydroxide**

Oral	LD50	2000 mg/kg (Rat)
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**hydrochloric acid**

Oral	LD50	900 mg/kg (Rabbit)
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**Primary irritant effect:**

**By Inhalation:**

Formulation contains some materials that are irritants. Inhaling small amounts of liquid aerosol may result in nasal and other respiratory tract irritation.

In general, depending on both the dose and duration, exposure to radioactive materials may produce adverse effects.

**By Ingestion:**

Inadvertent ingestion of trace amounts of this material would not be expected to result in symptoms.

However, ingestion of substantial amounts may cause kidney damage (acute tubular necrosis).

In general, depending on both the dose and duration, exposure to radioactive materials may produce adverse effects.

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Toxic effects of radiation may include development of cancer, adverse reproductive effects, including adverse effects on the fetus.

**on the skin:**

Material contains low concentration of components that are mild irritants or possible irritants. It may have potential to cause mild irritation, however, moderate or severe irritation is not expected. Acute skin exposure is not expected to exceed 50 mSV/year (Occupational Exposure Guideline)

**on the eyes:** Not Available.

**on the skin:** No irritant effect.

**on the eye:** No irritating effect.

**Sensitization:**

Biological effects from exposure to radioactive materials are based on exposures higher than those permitted in an occupational setting. No harmful effects are expected from CardioGen-82 under normal use conditions

**Sensitization:** No sensitizing effects known.

**Single Exposure (STOT - SE):** No further relevant information available

**Repeated Exposure (STOT - RE):** No further relevant information available

**Other information (about experimental toxicology):** No further relevant information available

**Carcinogenic categories**

**IARC (International Agency for Research on Cancer)**

None of the ingredients is listed.

**NTP (National Toxicology Program)**

None of the ingredients is listed.

**OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

**Additional toxicological information:**

Contact with small quantities of material for short periods is not expected to result in pharmacologic or toxic effects.

**12 Ecological information**

**Toxicity**

**Aquatic toxicity:**

**18282-10-5 TIN (IV) OXIDE**

EC50/48 h > 100 mg/l (Daphnia Magna)

NOEC/48h > 100 mg/l (Daphnia Magna)

**1310-73-2 Sodium Hydroxide**

LC50 180 mg/l (Fish)

**Persistence and degradability** No further relevant information available.

**Bioaccumulative potential** No further relevant information available.

**Mobility in soil:** No further relevant information available.

**Results of PBT and vPvB assessment**

**PBT:** Not applicable.

**vPvB:** Not applicable.

**Other adverse effects** No further relevant information available.

**Additional Information:** Use according to good working practice.

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### 13 Disposal considerations

**Waste treatment methods:**

**Recommendation:**

Must not be disposed of together with household garbage. Do not allow product to reach sewage system. Reutilise if possible or contact a waste processors for recycling or safe disposal.

**Uncleaned packagings:**

**Recommendation:**

Dispose of radioactive material in accordance with all local, state, federal and NRC regulations or with the regulations of the country in which the material is used.

**Recommended cleansing agent:** Not Available

### 14 Transport information

**UN-Number**

**DOT**

1. Domestic  
DOT shipping classification: Radioactive material- see US regulations regarding shipment of radioactive materials.

2. International

DOT shipping classification: Radioactive material- see US and other nations' regulations on shipment of radioactive materials.

**ADR**

1. Domestic

ADR shipping classification: Radioactive material- see US regulations regarding shipment of radioactive materials.

2. International

ADR shipping classification: Radioactive material- see US and other nations' regulations on shipment of radioactive materials.

**IMDG**

Not applicable.

1. Domestic

IMDG shipping classification: Radioactive material- see US regulations regarding shipment of radioactive materials.

2. International

IMDG shipping classification: Radioactive material- see US and other nations' regulations on shipment of radioactive materials.

**IATA**

1. Domestic

ICAO/IATA shipping classification: Radioactive material- see US regulations regarding shipment of radioactive materials.

2. International

ICAO/IATA shipping classification: Radioactive material- see US and other nations' regulations on shipment of radioactive materials.

**UN proper shipping name**

**DOT**

Void

**Packing group**

**DOT**

Void

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**Environmental hazards:**

**Marine pollutant:** No

**Special precautions for user:** Not applicable.

**Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code:** Not applicable.

### 15 Regulatory information

**Safety, health and environmental regulations/legislation specific for the substance or mixture**  
Sara

**Section 355 (extremely hazardous substances):**

None of the ingredients is listed.

**Section 313 (Specific toxic chemical listings):**

None of the ingredients is listed.

**TSCA (Toxic Substances Control Act):**

18282-10-5	TIN (IV) OXIDE
7647-14-5	sodium chloride
1310-73-2	Sodium Hydroxide
7440-24-6	Strontium <sup>82</sup> /Strontium <sup>85</sup> (**)

**Proposition 65**

**Chemicals known to cause cancer:**

None of the ingredients is listed.

**Chemicals known to cause reproductive toxicity for females:**

None of the ingredients is listed.

**Chemicals known to cause reproductive toxicity for males:**

None of the ingredients is listed.

**Chemicals known to cause developmental toxicity:**

None of the ingredients is listed.

**Carcinogenic categories**

**EPA (Environmental Protection Agency)**

None of the ingredients is listed.

**TLV (Threshold Limit Value established by ACGIH)**

None of the ingredients is listed.

**NIOSH-Ca (National Institute for Occupational Safety and Health)**

None of the ingredients is listed.

**GHS label elements** Not applicable.

**Hazard pictograms** Not applicable.

**Signal word** Not applicable.

**Hazard statements** Not applicable.

### 16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

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**Description and Property:**

The CardioGen-82 Rubidium Rb 82 Generator is a shielded column that contains a slurry of normal saline solution and stannic oxide to which Strontium Sr-82/Sr-85 has been adsorbed.

As in the use of any radioactive material, care should be taken to insure minimum radiation exposure.

**Significant Dangers:**

If ingestion of eluent from the CardioGen-82 generator (containing radioactive Rubidium-82) inadvertently occurs, the individual may be treated by water hydration or diuresis to facilitate elimination of the radioactive material.

**Relevant phrases**

H260 In contact with water releases flammable gases, which may ignite spontaneously.

H314 Causes severe skin burns and eye damage.

H335 May cause respiratory irritation.

**Training Hints:**

All persons handling this product should be informed on the existence of the hazard, on any possible risk they might be subjected to and about all required protective measures to prevent such a damage or to reduce the exposition.

**WARNINGS:**

When transporting an employee for medical assistance, after the employee has had direct contact with a radioactive material, care should be taken to avoid contamination of transport vehicle and medical facility. Skin decontamination and monitoring should be conducted as appropriate.

Radiopharmaceuticals should be used only by physicians who are qualified by training and experience in the safe use and handling of radionuclides) and whose experience and training have been approved by the appropriate government agency authorized to license the use of radionuclides.

Dispose of radioactive material in accordance with all local, state, federal and NRC regulations or with the regulations of the country in which the material is used.

**Department issuing SDS:**

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**Abbreviations and acronyms:**

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

ACGIH: American Conference of Governmental Industrial Hygienists

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

NFPA: National Fire Protection Association (USA)

HMS: Hazardous Materials Identification System (USA)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

Water-react. 1: Substances and Mixtures which, in contact with water, emit flammable gases, Hazard Category 1

Skin Corr. 1A: Skin corrosion/irritation, Hazard Category 1A

Skin Corr. 1B: Skin corrosion/irritation, Hazard Category 1B

STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3

**\* Data compared to the previous version altered.**

- data updating on the basis of the latest amendments.

- adaptation of the form according to Regulation 1907/2006/CE.