

Safety Data Sheet

According to OSHA HazCom Standard [2012]

Printing date 12/12/2018

Version 3

Reviewed on 12/12/2018

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.

CAS Number: 7791-11-9

Application of the substance / the mixture:

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

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.

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.

Details of the supplier of the safety data sheet

Manufacturer/Supplier:

Bracco Diagnostics Inc.

P.O. Box 5225

Princeton, NJ 08543

Phone number: 1-800-257-5181

Email: Hse@bracco.com (responsible for the SDS)

Information department:

B-Lands Consulting

WTC, 5 Place Robert Schuman, BP 1516

38025 Grenoble, FRANCE

Tel: +33 476 295 869

Fax: +33 476 295 870

Email: clients@reachteam.eu

www.reachteam.eu

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

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.

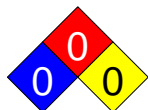
Signal word Not applicable.

Hazard statements Not applicable.

Additional Information:

Classification system:

NFPA ratings (scale 0 - 4)



Health = 0

Fire = 0

Reactivity = 0

HMIS-ratings (scale 0 - 4)



Health = 0

Fire = 0

Reactivity = 0

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Other hazards No further relevant information available.

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

3 Composition/information on ingredients

Chemical characterization: Mixtures

Description: Mixture: consisting of the following components.

Hazardous Components:

1310-73-2	Sodium Hydroxide	Skin Corr. 1A, H314; Acute Tox. 4, H302	≥2-<2.5%
7440-24-6	Strontium ⁸² /Strontium ⁸⁵ (**)	Water-react. 1, H260	≥0.1-<1%

Non-Hazardous Components:

18282-10-5	TIN (IV) OXIDE	10%
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Information on components:

18282-10-5	TIN (IV) OXIDE	10%
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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).

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. Consult doctor if symptoms persist.

After skin contact:

Immediately wash with water and soap and rinse thoroughly.

Seek medical attention if skin irritation, swelling or redness develops and persists.

Swab skin to verify all removable radioactive contamination is gone.

After eye contact:

Rinse immediately with plenty of water, also under the eyelids for at least 15 minutes. If irritation persists get medical attention.

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

After swallowing:

Immediately call a doctor.

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.

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Most important symptoms and effects, both acute and delayed

No further relevant information available.

Indication of any immediate medical attention and special treatment needed

No further relevant information available.

5 Fire-fighting measures

Extinguishing media

Suitable extinguishing agents: Water

Special hazards arising from the substance or mixture 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).

In addition, firefighters should wear flame and chemicals resistant clothing, boots and gloves.

6 Accidental release measures

Personal precautions, protective equipment and emergency procedures

Wear protective equipment. Keep unprotected persons away.

Radioactive shielding if appropriate to minimize exposure

Environmental precautions:

Do not allow product to reach sewage system or any water course.

Do not allow to penetrate the ground/soil.

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

Methods and material for containment and cleaning up:

Absorb with liquid-binding 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

No dangerous substances are released.

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

Protective Action Criteria for Chemicals

PAC-1:

None of the ingredients are listed.

PAC-2:

None of the ingredients are listed.

PAC-3:

None of the ingredients are listed.

7 Handling and storage

Precautions for safe handling

Avoid contact with the eyes and skin.

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.

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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.

Information about protection against explosions and fires: No special measures required.

Conditions for safe storage, including any incompatibilities

Requirements to be met by storerooms and receptacles:

Store in a cool, dry place in well sealed 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

Control parameters

Components with limit values that require monitoring at the workplace:

The following constituent is the only constituent of the product which has a PEL, TLV or other recommended exposure limit.

At this time, the remaining constituent has no known exposure limits.

1310-73-2 Sodium Hydroxide

TLV-ACGIH	Long-term value: 2 mg/m ³ 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 / m³ 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

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.



Do not eat, drink and 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:



Protective gloves

The glove material must be impermeable and resistant to the product/ the substance/ the preparation. Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

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

Material of gloves

Natural rubber, NR

Nitrile rubber, NBR

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. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

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:



Safety glasses

Body protection: Protective work clothing

9 Physical and chemical properties

Information on basic physical and chemical properties

General Information

Appearance:

Form:

Solid

Odor threshold:

Not determined.

pH-value:

Not applicable.

Melting point/Melting range:

Not determined.

Boiling point/Boiling range:

Not determined.

Flash point:

Not applicable.

Flammability (solid, gaseous):

Not determined.

Decomposition temperature:

Not determined.

Auto igniting:

Product is not selfigniting.

Danger of explosion:

Product does not present an explosion hazard.

Explosion limits:

Lower:

Not determined.

Upper:

Not determined.

Vapor pressure:

Not applicable.

Density:

Not determined.

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Relative density Not determined.

Vapor density Not applicable.

Evaporation rate Not applicable.

Solubility in / Miscibility with Water: Insoluble.

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

Viscosity:

Dynamic: Not applicable.

Kinematic: Not applicable.

Solids content: 11.0 %

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).

Thermal decomposition / conditions to be avoided:

No decomposition if used according to specifications.

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 dangerous decomposition products known.

11 Toxicological information

Information on toxicological effects

Acute toxicity:

LD/LC50 values that are relevant for classification:

18282-10-5 TIN (IV) OXIDE

Oral LD50 > 20000 mg/kg (Rat)

7647-14-5 sodium chloride

Oral LD50 3000 mg/kg (Rat)

1310-73-2 Sodium Hydroxide

Oral LD50 2000 mg/kg (Rat)

hydrochloric acid

Oral LD50 900 mg/kg (Rabbit)

Primary irritant effect:

on the skin:

No irritant effect.

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)

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on the eye: No irritating effect.

Sensitization:

No sensitizing effects known.

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

Other information (about experimental toxicology):

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.

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

Additional toxicological information:

The product is not subject to classification according to internally approved calculation methods for preparations.

When used and handled according to specifications, the product does not have any harmful effects to our experience and the information provided to us.

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

Carcinogenic categories

IARC (International Agency for Research on Cancer)

None of the ingredients are listed.

NTP (National Toxicology Program)

None of the ingredients are listed.

OSHA-Ca (Occupational Safety & Health Administration)

None of the ingredients are listed.

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.

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Other adverse effects No further relevant information available.

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.

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

Not applicable.

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Transport hazard class(es)

DOT



Class

Not applicable.

Label

90

Packing group

DOT

Not applicable.

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

This safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006.

Sara

Section 355 (extremely hazardous substances):

None of the ingredients are listed.

Section 313 (Specific toxic chemical listings):

None of the ingredients is listed.

TSCA new (21st Century Act) (Substances not listed)

1310-73-2 Sodium Hydroxide

7440-24-6 Strontium⁸²/Strontium⁸⁵(**)

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 are listed.

Chemicals known to cause reproductive toxicity for males:

None of the ingredients are listed.

Chemicals known to cause developmental toxicity:

None of the ingredients are listed.

Carcinogenic categories

EPA (Environmental Protection Agency)

None of the ingredients are listed.

TLV (Threshold Limit Value established by ACGIH)

None of the ingredients are listed.

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

None of the ingredients are listed.

GHS label elements Not applicable.

Hazard pictograms Not applicable.

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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.

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.

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.

Contact:

Bracco Diagnostics Inc.

P.O. Box 5225

Princeton, NJ 08543

Date of preparation / last revision 12/12/2018 / 2

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)

HMIS: 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 – Category 1

Acute Tox. 4: Acute toxicity – Category 4

Skin Corr. 1A: Skin corrosion/irritation – Category 1A

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

- data updating on the basis of the latest amendments.