

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



Roche CARDIAC POC NT-proBNP

Version
1.1

Revision Date:
30.05.2024

Date of last issue: 06.10.2022
Date of first issue: 06.10.2022

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name : Roche CARDIAC POC NT-proBNP
Product code : 09213074191

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Substance/Mixture : Laboratory chemicals, Refer to product literature for further details.

1.3 Details of the supplier of the safety data sheet

Company : Roche Diagnostics Deutschland GmbH
Sandhoferstrasse 116
68305 Mannheim
Deutschland

Telephone : +496217590
Telefax : +496217592890
Responsible Department : +49(0)621-759-4223
E-mail address : info.dia-sds@roche.com

1.4 Emergency telephone number

In case of emergencies: : Central Works Security +49(0)621-759-2203
Roche Diagnostics GmbH

Centre for detoxification: : Mainz +49(0)6131-19240

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) required

Additional Labelling

EUH210 Safety data sheet available on request.

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

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Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

| Chemical name | CAS-No. EC-No. Index-No. Registration number | Classification | Concentration (% w/w) |
|---|---|--------------------------------------|--------------------------|
| glass, oxide, chemicals | 65997-17-3 266-046-0 | Skin Irrit. 2; H315 Carc. 2; H351 | >= 1,0 - < 10,0 |
| Mineral wool with alkaline- and alkali earth oxide >18% | Not Assigned 650-016-00-2 | Carc. 2; H351 | >= 1,0 - < 10,0 |
| cellulose nitrate | 9004-70-0 603-037-00-6 | Expl. 1.1; H201 | >= 1,0 - < 10,0 |

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

- General advice : Do not leave the victim unattended.
- If inhaled : Move to fresh air.
If unconscious, place in recovery position and seek medical advice.
If symptoms persist, call a physician.
- In case of skin contact : If skin irritation persists, call a physician.
If on skin, rinse well with water.
If on clothes, remove clothes.
- In case of eye contact : Immediately flush eye(s) with plenty of water.
Remove contact lenses.
Protect unharmed eye.
Keep eye wide open while rinsing.

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If eye irritation persists, consult a specialist.

If swallowed : Keep respiratory tract clear.
Do not give milk or alcoholic beverages.
Never give anything by mouth to an unconscious person.
If symptoms persist, call a physician.
Rinse mouth with water.

4.2 Most important symptoms and effects, both acute and delayed

None known.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : The first aid procedure should be established in consultation with the doctor responsible for industrial medicine.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable extinguishing media : High volume water jet

5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-fighting : No information available.

Hazardous combustion products : No hazardous combustion products are known

5.3 Advice for firefighters

Special protective equipment for firefighters : Wear self-contained breathing apparatus for firefighting if necessary.

Further information : Standard procedure for chemical fires.
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.
Avoid dust formation.
Avoid breathing dust.

6.2 Environmental precautions

Environmental precautions : Prevent further leakage or spillage if safe to do so.
Local authorities should be advised if significant spillages cannot be contained.

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6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Keep in suitable, closed containers for disposal.

6.4 Reference to other sections

Treat recovered material as described in the section "Disposal considerations".

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Advice on safe handling : Avoid contact with skin and eyes.
For personal protection see section 8.
Smoking, eating and drinking should be prohibited in the application area.
Dispose of rinse water in accordance with local and national regulations.

Advice on protection against fire and explosion : Avoid dust formation. Provide appropriate exhaust ventilation at places where dust is formed.

Hygiene measures : When using do not eat or drink. When using do not smoke.
Wash hands before breaks and at the end of workday.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : Keep container tightly closed in a dry and well-ventilated place. Electrical installations / working materials must comply with the technological safety standards.

Further information on storage conditions : See label, package insert or internal guidelines

Storage class (TRGS 510) : 13

Further information on storage stability : No decomposition if stored and applied as directed.

7.3 Specific end use(s)

Specific use(s) : Laboratory chemicals

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Contains no substances with occupational exposure limit values.

8.2 Exposure controls

Engineering measures

No data available

Personal protective equipment

Eye/face protection : Use eye protection according to EN 166.

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Eye wash bottle with pure water
Tightly fitting safety goggles

Hand protection

In case of contact through splashing:
Material : Nitrile rubber
Break through time : > 30 min
Glove thickness : > 0,11 mm

In case of full contact:
Material : butyl-rubber
Break through time : > 480 min
Glove thickness : > 0,4 mm

Remarks : The selected protective gloves have to satisfy the specifications of Regulation (EU) 2016/425 and the standard EN 374 derived from it. This recommendation is only valid for the product mentioned in the safety data sheet and provided by us and for the application specified by us. Please observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves. Also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion, and the contact time. The suitability for a specific workplace should be discussed with the producers of the protective gloves.

Skin and body protection : Choose body protection according to the amount and concentration of the dangerous substance at the work place.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state : solid
Colour : No data available
Odour : Not applicable
Odour Threshold : Not applicable
Melting point/range : No data available
Boiling point/boiling range : No data available
Flammability : Does not sustain combustion.
Upper explosion limit / Upper flammability limit : No data available
Lower explosion limit / Lower flammability limit : No data available

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| | | |
|--|---|-------------------|
| Flash point | : | does not flash |
| Auto-ignition temperature | : | No data available |
| Decomposition temperature | : | No data available |
| pH | : | Not applicable |
| Viscosity | | |
| Viscosity, dynamic | : | Not applicable |
| Viscosity, kinematic | : | Not applicable |
| Solubility(ies) | | |
| Water solubility | : | insoluble |
| Solubility in other solvents | : | No data available |
| Partition coefficient: n-octanol/water | : | No data available |
| Vapour pressure | : | No data available |
| Relative density | : | No data available |
| Relative vapour density | : | Not applicable |
| Particle characteristics | | |
| Particle Size Distribution | : | No data available |

9.2 Other information

| | | |
|------------------------|---|--|
| Explosives | : | Not explosive |
| Oxidizing properties | : | The substance or mixture is not classified as oxidizing. |
| Flammability (liquids) | : | Does not sustain combustion. |
| Self-ignition | : | No data available |
| Evaporation rate | : | No data available |

SECTION 10: Stability and reactivity

10.1 Reactivity

No dangerous reaction known under conditions of normal use.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : No decomposition if stored and applied as directed.

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10.4 Conditions to avoid

Conditions to avoid : No data available

10.5 Incompatible materials

Materials to avoid : No data available

10.6 Hazardous decomposition products

No data available

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity

Not classified due to lack of data.

Components:

cellulose nitrate:

Acute oral toxicity : LD50 Oral (Rat): > 5.000 mg/kg

Skin corrosion/irritation

Not classified due to lack of data.

Product:

Remarks : May cause skin irritation and/or dermatitis.

Components:

glass, oxide, chemicals:

Result : Irritating to skin.

Mineral wool with alkaline- and alkali earth oxide >18%:

Remarks : This information is not available.

Serious eye damage/eye irritation

Not classified due to lack of data.

Product:

Remarks : Product dust may be irritating to eyes, skin and respiratory system.

Components:

Mineral wool with alkaline- and alkali earth oxide >18%:

Remarks : This information is not available.

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Respiratory or skin sensitisation

Skin sensitisation

Not classified due to lack of data.

Respiratory sensitisation

Not classified due to lack of data.

Germ cell mutagenicity

Not classified due to lack of data.

Carcinogenicity

Based on available data, the classification criteria are not met.

Product:

Carcinogenicity - Assessment : Weight of evidence does not support classification as a carcinogen

Components:

glass, oxide, chemicals:

Carcinogenicity - Assessment : Limited evidence of a carcinogenic effect.

Mineral wool with alkaline- and alkali earth oxide >18%:

Carcinogenicity - Assessment : Limited evidence of a carcinogenic effect.

Reproductive toxicity

Not classified due to lack of data.

STOT - single exposure

Not classified due to lack of data.

STOT - repeated exposure

Not classified due to lack of data.

Aspiration toxicity

Not classified due to lack of data.

Components:

Mineral wool with alkaline- and alkali earth oxide >18%:

No data available

11.2 Information on other hazards

Endocrine disrupting properties

Product:

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

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SECTION 12: Ecological information

12.1 Toxicity

Components:

Mineral wool with alkaline- and alkali earth oxide >18%:

Ecotoxicology Assessment

Toxicity Data on Soil : Not expected to adsorb on soil.

Other organisms relevant to the environment : No data available

cellulose nitrate:

Toxicity to fish : LC50 (Danio rerio (zebra fish)): > 10.000 mg/l
Exposure time: 96 h

Toxicity to microorganisms : EC50 (Bacteria): > 10.000 mg/l

Ecotoxicology Assessment

Toxicity Data on Soil : Not expected to adsorb on soil.

Other organisms relevant to the environment : No data available

12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential

Components:

glass, oxide, chemicals:

Partition coefficient: n-octanol/water : Remarks: No data available

Mineral wool with alkaline- and alkali earth oxide >18%:

Partition coefficient: n-octanol/water : Remarks: No data available

cellulose nitrate:

Partition coefficient: n-octanol/water : Remarks: No data available

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

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Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Endocrine disrupting properties

Product:

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product : Do not contaminate ponds, waterways or ditches with chemical or used container.
Send to a licensed waste management company.

Contaminated packaging : Empty remaining contents.
Dispose of as unused product.
Empty containers should be taken to an approved waste handling site for recycling or disposal.
Do not re-use empty containers.

SECTION 14: Transport information

14.1 UN number or ID number

ADR : Not regulated as a dangerous good
RID : Not regulated as a dangerous good
IMDG : Not regulated as a dangerous good
IATA : Not regulated as a dangerous good

14.2 UN proper shipping name

ADR : Not regulated as a dangerous good
RID : Not regulated as a dangerous good
IMDG : Not regulated as a dangerous good
IATA : Not regulated as a dangerous good

14.3 Transport hazard class(es)

ADR : Not regulated as a dangerous good
RID : Not regulated as a dangerous good

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IMDG : Not regulated as a dangerous good

IATA : Not regulated as a dangerous good

14.4 Packing group

ADR : Not regulated as a dangerous good

RID : Not regulated as a dangerous good

IMDG : Not regulated as a dangerous good

IATA (Cargo) : Not regulated as a dangerous good

IATA (Passenger) : Not regulated as a dangerous good

14.5 Environmental hazards

Not regulated as a dangerous good

14.6 Special precautions for user

Remarks : Not dangerous goods in the meaning of ADR/RID, ADN, IMDG-Code, ICAO/IATA-DGR

14.7 Maritime transport in bulk according to IMO instruments

Remarks : Not applicable

SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) : Not applicable

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). : Not applicable

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable

Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable

REACH - List of substances subject to authorisation (Annex XIV) : Not applicable

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major- : Not applicable

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accident hazards involving dangerous substances.

Water hazard class (Germany) : WGK 1 slightly hazardous to water
Classification according to AwSV, Annex 1 (5.2)

TA Luft List (Germany) : 5.2.1: Total dust:
others: < 0,01 % Sodium citrate dihydrate
5.2.2: Inorganic substances in powdered form:
Not applicable
5.2.4: Inorganic substances in gaseous form:
Not applicable
5.2.5: Organic Substances:
Not applicable
5.2.7.1.1: Carcinogenic substance:
Not applicable
5.2.7.1.1: Quartz fine dust PM4:
Not applicable
5.2.7.1.1: Formaldehyde:
Not applicable
5.2.7.1.1: fibres:
Not applicable
5.2.7.1.2: Germ cell mutagens:
Not applicable
5.2.7.1.3: Substances toxic to reproduction:
Not applicable
5.2.7.2: Poorly degradable, easily enrichable and highly toxic organic substances:
Not applicable

Volatile organic compounds : Directive 2010/75/EU of 24 November 2010 on industrial emissions (integrated pollution prevention and control)
Volatile organic compounds (VOC) content: 0,02 %

Other regulations:

Take note of Law on the protection of mothers at work, in education and in studies (Maternity Protection Act - MuSchG).

Take note of Law on the protection of mothers at work, in education and in studies (Maternity Protection Act - MuSchG).

The components of this product are reported in the following inventories:

AIIC : Not in compliance with the inventory

DSL : This product contains the following components that are not on the Canadian DSL nor NDSL.

non hazardous compounds
non hazardous compounds (solid) (Finally reviewed)
Mineral wool with alkaline- and alkali earth oxide >18%
Albumins, beef serum
1-O-octyl-β-D-glucopyranoside
Antibodies

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Streptavidin Poly, SAMBA cross-linked
proBNP(24-34)-Polyhapten

| | | |
|-------|---|---|
| NZIoC | : | On the inventory, or in compliance with the inventory |
| ENCS | : | Not in compliance with the inventory |
| ISHL | : | Not in compliance with the inventory |
| KECI | : | Not in compliance with the inventory |
| PICCS | : | Not in compliance with the inventory |
| IECSC | : | Not in compliance with the inventory |
| TCSI | : | Not in compliance with the inventory |
| TSCA | : | Product contains substance(s) not listed on TSCA inventory. |
| TECI | : | Not in compliance with the inventory |

15.2 Chemical safety assessment

Chemical Safety Assessments for all substances in this product are either Complete or Not applicable.

SECTION 16: Other information

Full text of H-Statements

| | | |
|------|---|-----------------------------------|
| H201 | : | Explosive; mass explosion hazard. |
| H315 | : | Causes skin irritation. |
| H351 | : | Suspected of causing cancer. |

Full text of other abbreviations

| | | |
|-------------|---|-----------------|
| Carc. | : | Carcinogenicity |
| Expl. | : | Explosives |
| Skin Irrit. | : | Skin irritation |

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - Interna-

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tional Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

Further information

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

DE / EN / 2304