

## Roche CARDIAC Control D-Dimer

Version 1.20	Revision Date: 01.02.2022	Date of last issue: 14.08.2021 Date of first issue: 18.07.2012
-----------------	------------------------------	---

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

#### 1.1 Product identifier

Trade name : Roche CARDIAC Control D-Dimer  
Product code : 04890523190

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

Recommended restrictions on use : For professional users only.

#### 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  
Munich +49(0)89-19240

### SECTION 2: Hazards identification

#### 2.1 Classification of the substance or mixture

The product is a kit consisting of individual ingredients. The classification of the ingredients can be obtained from section 3. Section Label elements contains the resulting labelling for the kit.

#### 2.2 Label elements

##### Labelling (REGULATION (EC) No 1272/2008)

Hazard statements : H412 Harmful to aquatic life with long lasting effects.

Precautionary statements : **Prevention:**  
P273 Avoid release to the environment.

**Disposal:**  
P501 Dispose of contents/ container to an approved waste

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Roche CARDIAC Control D-Dimer

Version  
1.20

Revision Date:  
01.02.2022

Date of last issue: 14.08.2021  
Date of first issue: 18.07.2012

disposal plant.

### 2.3 Other hazards

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

### Contr. low - level 1

#### Classification (REGULATION (EC) No 1272/2008)

Long-term (chronic) aquatic hazard, Category 3

H412: Harmful to aquatic life with long lasting effects.

Chemical nature : Handle as potentially infectious.

#### Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
sodium azide	26628-22-8 247-852-1 011-004-00-7 01-2119457019-37	Acute Tox. 2; H300 Acute Tox. 2; H330 Acute Tox. 1; H310 STOT RE 2; H373 Aquatic Acute 1; H400 Aquatic Chronic 1; H410 EUH032  Acute toxicity estimate  Acute oral toxicity: 27 mg/kg Acute inhalation toxicity (dust/mist): > 0,05 mg/l Acute dermal toxicity: 20 mg/kg	>= 0,25 - < 1,0

For explanation of abbreviations see section 16.

### Contr. high - level 2

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Roche CARDIAC Control D-Dimer

Version  
1.20

Revision Date:  
01.02.2022

Date of last issue: 14.08.2021  
Date of first issue: 18.07.2012

### Classification (REGULATION (EC) No 1272/2008)

Long-term (chronic) aquatic hazard, Category 3 H412: Harmful to aquatic life with long lasting effects.

Chemical nature : Handle as potentially infectious.

### Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
sodium azide	26628-22-8 247-852-1 011-004-00-7 01-2119457019-37	Acute Tox. 2; H300 Acute Tox. 2; H330 Acute Tox. 1; H310 STOT RE 2; H373 Aquatic Acute 1; H400 Aquatic Chronic 1; H410 EUH032  Acute toxicity estimate  Acute oral toxicity: 27 mg/kg Acute inhalation toxicity (dust/mist): > 0,05 mg/l Acute dermal toxicity: 20 mg/kg	>= 0,25 - < 1,0

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 on skin, rinse well with water.

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.

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Roche CARDIAC Control D-Dimer

Version  
1.20

Revision Date:  
01.02.2022

Date of last issue: 14.08.2021  
Date of first issue: 18.07.2012

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

Symptoms : No information available.

### 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 : Do not allow run-off from fire fighting to enter drains or water courses.

### 5.3 Advice for firefighters

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

Further information : Collect contaminated fire extinguishing water separately. This must not be discharged into drains.  
Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.

---

## SECTION 6: Accidental release measures

### 6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Refer to protective measures listed in sections 7 and 8.

### 6.2 Environmental precautions

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

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Roche CARDIAC Control D-Dimer

Version  
1.20

Revision Date:  
01.02.2022

Date of last issue: 14.08.2021  
Date of first issue: 18.07.2012

### 6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Wipe up with absorbent material (e.g. cloth, fleece).  
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 : 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 : Normal measures for preventive fire protection.

Hygiene measures : 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. Containers which are opened must be carefully resealed and kept upright to prevent leakage. 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) : 12, Non Combustible Liquids

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

**Contr. low - level 1**

#### Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
sodium azide	26628-22-8	TWA	0,1 mg/m <sup>3</sup>	2000/39/EC

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Roche CARDIAC Control D-Dimer

Version  
1.20

Revision Date:  
01.02.2022

Date of last issue: 14.08.2021  
Date of first issue: 18.07.2012

	Further information: Identifies the possibility of significant uptake through the skin, Indicative		
	STEL	0,3 mg/m <sup>3</sup>	2000/39/EC
	Further information: Identifies the possibility of significant uptake through the skin, Indicative		
	AGW	0,2 mg/m <sup>3</sup>	DE TRGS 900
	Peak-limit: excursion factor (category): 2;(l)		

### Contr. high - level 2

#### Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
sodium azide	26628-22-8	TWA	0,1 mg/m <sup>3</sup>	2000/39/EC
	Further information: Identifies the possibility of significant uptake through the skin, Indicative			
		STEL	0,3 mg/m <sup>3</sup>	2000/39/EC
	Further information: Identifies the possibility of significant uptake through the skin, Indicative			
		AGW	0,2 mg/m <sup>3</sup>	DE TRGS 900
	Peak-limit: excursion factor (category): 2;(l)			

## 8.2 Exposure controls

### Engineering measures

No data available

### Personal protective equipment

Eye protection : Eye wash bottle with pure water  
Tightly fitting safety goggles

Use eye protection according to EN 166.

### 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

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Roche CARDIAC Control D-Dimer

Version  
1.20

Revision Date:  
01.02.2022

Date of last issue: 14.08.2021  
Date of first issue: 18.07.2012

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 : Impervious clothing  
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

##### **Contr. low - level 1**

Physical state : liquid

Colour : No data available

Odour : No data available

Odour Threshold : No data available

Melting point/range : No data available

Boiling point/boiling range : No data available

Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Flash point : does not flash

Auto-ignition temperature : No data available

Decomposition temperature : No data available

pH : No data available

Viscosity

    Viscosity, dynamic : No data available

    Viscosity, kinematic : No data available

Solubility(ies)

    Water solubility : completely miscible

    Solubility in other solvents : No data available

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

**Roche CARDIAC Control D-Dimer**

Version  
1.20

Revision Date:  
01.02.2022

Date of last issue: 14.08.2021  
Date of first issue: 18.07.2012

Vapour pressure : No data available  
Relative density : No data available  
Relative vapour density : No data available

**Contr. high - level 2**

Physical state : liquid  
Colour : No data available  
Odour : No data available  
Odour Threshold : No data available  
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  
Flash point : does not flash  
Auto-ignition temperature : No data available  
Decomposition temperature : No data available  
pH : No data available  
Viscosity  
    Viscosity, dynamic : No data available  
    Viscosity, kinematic : No data available  
Solubility(ies)  
    Water solubility : completely miscible  
    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



## Roche CARDIAC Control D-Dimer

Version  
1.20

Revision Date:  
01.02.2022

Date of last issue: 14.08.2021  
Date of first issue: 18.07.2012

Relative vapour density : No data available

### 9.2 Other information

#### **Contr. low - level 1**

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Self-ignition : No data available

Evaporation rate : No data available

Miscibility with water : No data available

#### **Contr. high - level 2**

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

Miscibility with water : 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.

### 10.4 Conditions to avoid

Conditions to avoid : No data available

### 10.5 Incompatible materials

Materials to avoid : No data available

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Roche CARDIAC Control D-Dimer

Version  
1.20

Revision Date:  
01.02.2022

Date of last issue: 14.08.2021  
Date of first issue: 18.07.2012

### 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

#### **Contr. low - level 1**

##### **Acute toxicity**

Not classified based on available information.

##### **Components:**

##### **sodium azide:**

- Acute oral toxicity : LD50 Oral (Rat): 27 mg/kg  
Acute toxicity estimate: 27 mg/kg  
Method: Calculation method
- Acute inhalation toxicity : LC50: 0,053 - 0,52 mg/l  
Test atmosphere: dust/mist  
Target Organs: Respiratory system  
Acute toxicity estimate: > 0,05 mg/l  
Test atmosphere: dust/mist  
Method: Expert judgement
- Acute dermal toxicity : LD50 Dermal (Rabbit): 20 mg/kg  
Acute toxicity estimate: 20 mg/kg  
Method: Calculation method

##### **Skin corrosion/irritation**

Not classified based on available information.

##### **Components:**

##### **sodium azide:**

- Method : OECD Test Guideline 439  
Result : No skin irritation

##### **Serious eye damage/eye irritation**

Not classified based on available information.

##### **Components:**

##### **sodium azide:**

- Species : Bovine cornea  
Exposure time : 4 h  
Method : OECD Test Guideline 437  
Result : No eye irritation

## Roche CARDIAC Control D-Dimer

Version  
1.20

Revision Date:  
01.02.2022

Date of last issue: 14.08.2021  
Date of first issue: 18.07.2012

### Respiratory or skin sensitisation

#### Skin sensitisation

Not classified based on available information.

#### Respiratory sensitisation

Not classified based on available information.

#### Components:

##### sodium azide:

Test Type : Local lymph node assay (LLNA)  
Species : Mouse  
Method : OECD Test Guideline 429  
Result : negative

Assessment : Fatal if inhaled.

#### Germ cell mutagenicity

Not classified based on available information.

#### Components:

##### sodium azide:

Genotoxicity in vitro : Test Type: Chromosome aberration test in vitro  
Test system: Chinese hamster ovary cells  
Result: negative

Test Type: sister chromatid exchange assay  
Test system: Chinese hamster ovary cells  
Result: negative

Test Type: unscheduled DNA synthesis assay  
Test system: Chinese hamster lung cells  
Result: negative

#### Carcinogenicity

Not classified based on available information.

#### Reproductive toxicity

Not classified based on available information.

#### STOT - single exposure

Not classified based on available information.

#### STOT - repeated exposure

Not classified based on available information.

#### Components:

##### sodium azide:

Assessment : May cause damage to organs through prolonged or repeated exposure.

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Roche CARDIAC Control D-Dimer

Version  
1.20

Revision Date:  
01.02.2022

Date of last issue: 14.08.2021  
Date of first issue: 18.07.2012

### Repeated dose toxicity

#### Components:

##### sodium azide:

Species : Rat  
NOAEL : 5 mg/kg  
LOAEL : 10 mg/kg  
Application Route : Oral  
Exposure time : 24 Months  
Method : OECD Test Guideline 453

Species : Rat  
NOAEL : 10 mg/kg  
LOAEL : 20 mg/kg  
Application Route : Oral  
Exposure time : 90 d

### Aspiration toxicity

Not classified based on available information.

### **Contr. high - level 2**

#### Acute toxicity

Not classified based on available information.

#### Components:

##### sodium azide:

Acute oral toxicity : LD50 Oral (Rat): 27 mg/kg  
Acute toxicity estimate: 27 mg/kg  
Method: Calculation method

Acute inhalation toxicity : LC50: 0,053 - 0,52 mg/l  
Test atmosphere: dust/mist  
Target Organs: Respiratory system  
Acute toxicity estimate: > 0,05 mg/l  
Test atmosphere: dust/mist  
Method: Expert judgement

Acute dermal toxicity : LD50 Dermal (Rabbit): 20 mg/kg  
Acute toxicity estimate: 20 mg/kg  
Method: Calculation method

### Skin corrosion/irritation

Not classified based on available information.

#### Components:

##### sodium azide:

Method : OECD Test Guideline 439  
Result : No skin irritation

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Roche CARDIAC Control D-Dimer

Version  
1.20

Revision Date:  
01.02.2022

Date of last issue: 14.08.2021  
Date of first issue: 18.07.2012

### Serious eye damage/eye irritation

Not classified based on available information.

#### Components:

##### sodium azide:

Species : Bovine cornea  
Exposure time : 4 h  
Method : OECD Test Guideline 437  
Result : No eye irritation

### Respiratory or skin sensitisation

#### Skin sensitisation

Not classified based on available information.

#### Respiratory sensitisation

Not classified based on available information.

#### Components:

##### sodium azide:

Test Type : Local lymph node assay (LLNA)  
Species : Mouse  
Method : OECD Test Guideline 429  
Result : negative

Assessment : Fatal if inhaled.

### Germ cell mutagenicity

Not classified based on available information.

#### Components:

##### sodium azide:

Genotoxicity in vitro : Test Type: Chromosome aberration test in vitro  
Test system: Chinese hamster ovary cells  
Result: negative

Test Type: sister chromatid exchange assay  
Test system: Chinese hamster ovary cells  
Result: negative

Test Type: unscheduled DNA synthesis assay  
Test system: Chinese hamster lung cells  
Result: negative

### Carcinogenicity

Not classified based on available information.

### Reproductive toxicity

Not classified based on available information.

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Roche CARDIAC Control D-Dimer

Version  
1.20

Revision Date:  
01.02.2022

Date of last issue: 14.08.2021  
Date of first issue: 18.07.2012

### STOT - single exposure

Not classified based on available information.

### STOT - repeated exposure

Not classified based on available information.

### Components:

#### sodium azide:

Assessment : May cause damage to organs through prolonged or repeated exposure.

### Repeated dose toxicity

#### Components:

#### sodium azide:

Species : Rat  
NOAEL : 5 mg/kg  
LOAEL : 10 mg/kg  
Application Route : Oral  
Exposure time : 24 Months  
Method : OECD Test Guideline 453

Species : Rat  
NOAEL : 10 mg/kg  
LOAEL : 20 mg/kg  
Application Route : Oral  
Exposure time : 90 d

### Aspiration toxicity

Not classified based on available information.

## 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.

## Contr. low - level 1

### 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.

## Roche CARDIAC Control D-Dimer

Version  
1.20

Revision Date:  
01.02.2022

Date of last issue: 14.08.2021  
Date of first issue: 18.07.2012

### **Contr. high - level 2**

#### **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.

---

## **SECTION 12: Ecological information**

### **12.1 Toxicity**

#### **Contr. low - level 1**

##### **Components:**

##### **sodium azide:**

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 5,46 mg/l  
Exposure time: 96 h  
Test Type: flow-through test  
Method: OECD Test Guideline 203

LC50 (Oncorhynchus mykiss (rainbow trout)): 2,84 mg/l  
Exposure time: 96 h  
Test Type: flow-through test  
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 0,4 mg/l  
Exposure time: 48 h

Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): 0,35 mg/l  
Exposure time: 96 h  
Test Type: static test  
Method: OECD Test Guideline 201

Toxicity to microorganisms : EC50 (Tetrahymena pyriformis): 5,6 mg/l

##### **Ecotoxicology Assessment**

Acute aquatic toxicity : Very toxic to aquatic life.

Chronic aquatic toxicity : Very toxic to aquatic life with long lasting effects.

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

### **Contr. high - level 2**

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Roche CARDIAC Control D-Dimer

Version  
1.20

Revision Date:  
01.02.2022

Date of last issue: 14.08.2021  
Date of first issue: 18.07.2012

### Components:

#### **sodium azide:**

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 5,46 mg/l  
Exposure time: 96 h  
Test Type: flow-through test  
Method: OECD Test Guideline 203

LC50 (Oncorhynchus mykiss (rainbow trout)): 2,84 mg/l  
Exposure time: 96 h  
Test Type: flow-through test  
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 0,4 mg/l  
Exposure time: 48 h

Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): 0,35 mg/l  
Exposure time: 96 h  
Test Type: static test  
Method: OECD Test Guideline 201

Toxicity to microorganisms : EC50 (Tetrahymena pyriformis): 5,6 mg/l

### **Ecotoxicology Assessment**

Acute aquatic toxicity : Very toxic to aquatic life.

Chronic aquatic toxicity : Very toxic to aquatic life with long lasting effects.

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

## 12.2 Persistence and degradability

### **Contr. low - level 1**

#### Components:

#### **sodium azide:**

Biodegradability : Remarks: The methods for determining biodegradability are not applicable to inorganic substances.

### **Contr. high - level 2**

#### Components:

#### **sodium azide:**

Biodegradability : Remarks: The methods for determining biodegradability are not applicable to inorganic substances.

## 12.3 Bioaccumulative potential

### **Contr. low - level 1**



## Roche CARDIAC Control D-Dimer

Version  
1.20

Revision Date:  
01.02.2022

Date of last issue: 14.08.2021  
Date of first issue: 18.07.2012

### Components:

#### **sodium azide:**

Partition coefficient: n-octanol/water : Remarks: Not applicable

### **Contr. high - level 2**

### Components:

#### **sodium azide:**

Partition coefficient: n-octanol/water : Remarks: Not applicable

### 12.4 Mobility in soil

#### **Contr. low - level 1**

No data available

#### **Contr. high - level 2**

No data available

### 12.5 Results of PBT and vPvB assessment

#### **Contr. low - level 1**

Not relevant

#### **Contr. high - level 2**

Not relevant

### 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.

#### **Contr. low - level 1**

#### 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.

#### **Contr. high - level 2**

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.

## Roche CARDIAC Control D-Dimer

Version  
1.20

Revision Date:  
01.02.2022

Date of last issue: 14.08.2021  
Date of first issue: 18.07.2012

### 12.7 Other adverse effects

#### **Contr. low - level 1**

No data available

#### **Contr. high - level 2**

No data available

---

## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

- Product : Special treatment as infectious material is mandatory in compliance with local regulations (disinfection and incineration). The product should not be allowed to enter drains, water courses or the soil.  
Do not contaminate ponds, waterways or ditches with chemical or used container.  
Send to a licensed waste management company.  
Can be disposed as waste water, when in compliance with local regulations.
- 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

Not regulated as a dangerous good

### 14.2 UN proper shipping name

Not regulated as a dangerous good

### 14.3 Transport hazard class(es)

Not regulated as a dangerous good

### 14.4 Packing group

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

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Roche CARDIAC Control D-Dimer

Version  
1.20

Revision Date:  
01.02.2022

Date of last issue: 14.08.2021  
Date of first issue: 18.07.2012

### SECTION 15: Regulatory information

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

Seveso III: Directive : Not applicable  
2012/18/EU of the European  
Parliament and of the Council  
on the control of major-  
accident hazards involving  
dangerous substances.

Water hazard class (Germa- : WGK 1 slightly hazardous to water  
ny)

#### **Contr. low - level 1**

REACH - Restrictions on the manufacture, placing on : Conditions of restriction for the fol-  
the market and use of certain dangerous substances, lowing entries should be considered:  
preparations and articles (Annex XVII) Number on list 3

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

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

Regulation (EU) 2019/1021 on persistent organic pollu- : Not applicable  
tants (recast)

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

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

#### **Other regulations:**

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 (liquid)

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Roche CARDIAC Control D-Dimer

Version  
1.20

Revision Date:  
01.02.2022

Date of last issue: 14.08.2021  
Date of first issue: 18.07.2012

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
Volatile organic compounds	:	Directive 2010/75/EU of 24 November 2010 on industrial emissions (integrated pollution prevention and control) Not applicable

### Labelling (REGULATION (EC) No 1272/2008)

Hazard statements : H412 Harmful to aquatic life with long lasting effects.

Precautionary statements : **Prevention:**  
P273 Avoid release to the environment.  
**Disposal:**  
P501 Dispose of contents/ container to an approved waste disposal plant.

### Contr. high - level 2

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII)	:	Conditions of restriction for the following entries should be considered: Number on list 3
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

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Roche CARDIAC Control D-Dimer

Version  
1.20

Revision Date:  
01.02.2022

Date of last issue: 14.08.2021  
Date of first issue: 18.07.2012

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

### Other regulations:

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 (liquid)

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

Volatile organic compounds : Directive 2010/75/EU of 24 November 2010 on industrial emissions (integrated pollution prevention and control)  
Not applicable

### Labelling (REGULATION (EC) No 1272/2008)

Hazard statements : H412 Harmful to aquatic life with long lasting effects.

Precautionary statements : **Prevention:**  
P273 Avoid release to the environment.

**Disposal:**  
P501 Dispose of contents/ container to an approved waste disposal plant.

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Roche CARDIAC Control D-Dimer

Version  
1.20

Revision Date:  
01.02.2022

Date of last issue: 14.08.2021  
Date of first issue: 18.07.2012

### 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

H300	:	Fatal if swallowed.
H310	:	Fatal in contact with skin.
H330	:	Fatal if inhaled.
H373	:	May cause damage to organs through prolonged or repeated exposure.
H400	:	Very toxic to aquatic life.
H410	:	Very toxic to aquatic life with long lasting effects.

#### Full text of other abbreviations

Acute Tox.	:	Acute toxicity
Aquatic Acute	:	Short-term (acute) aquatic hazard
Aquatic Chronic	:	Long-term (chronic) aquatic hazard
STOT RE	:	Specific target organ toxicity - repeated exposure

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AIIIC - 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 - International 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

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Roche CARDIAC Control D-Dimer

Version  
1.20

Revision Date:  
01.02.2022

Date of last issue: 14.08.2021  
Date of first issue: 18.07.2012

---

### 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 / 2104