

## CoaguChek® PT Controls

Version	Revision Date:	Date of last issue: 16.08.2021
1.12	06.02.2022	Date of first issue: 14.08.2015

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

#### 1.1 Product identifier

Trade name : CoaguChek® PT Controls  
Product code : 07682573003

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

Recommended restrictions : For professional users only.  
on use

#### 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)

Not a hazardous substance or mixture.

#### 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.

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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

#### **PT Level 2**

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

Not a hazardous substance or mixture.

##### **Components**

Remarks : No hazardous ingredients

#### **PTCE/ACT/aPTT Bulb red**

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

Not a hazardous substance or mixture.

##### **Components**

Remarks : No hazardous ingredients

### 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.  
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.

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### 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.

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## SECTION 5: Firefighting measures

### 5.1 Extinguishing media

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

### 5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-fighting : No information available.

### 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.

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## 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 : Local authorities should be advised if significant spillages cannot be contained.

### 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".

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## 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.

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according to Regulation (EC) No. 1907/2006



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Advice on protection against fire and explosion : Normal measures for preventive fire protection.

Hygiene measures : Handle in accordance with good industrial hygiene and safety practice.

### 7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : Electrical installations / working materials must comply with the technological safety standards.

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

Advice on common storage : No materials to be especially mentioned.

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

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## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

#### ***PT Level 2***

Contains no substances with occupational exposure limit values.

#### ***PTCE/ACT/aPTT Bulb red***

Contains no substances with occupational exposure limit values.

### 8.2 Exposure controls

#### **Engineering measures**

No data available

#### **Personal protective equipment**

Eye protection : Safety glasses

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

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	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	: Protective suit
Respiratory protection	: No personal respiratory protective equipment normally required.

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

#### **PT Level 2**

Physical state	: (lyophilised)
Colour	: light yellow
Odour	: none
Odour Threshold	: Not applicable
Melting point/range	: No data available
Boiling point/boiling range	: No data available
Flammability	: Sustains 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

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pH	:	Not applicable
Viscosity		
Viscosity, dynamic	:	Not applicable
Viscosity, kinematic	:	Not applicable
Solubility(ies)		
Water solubility	:	soluble
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

### ***PTCE/ACT/aPTT Bulb red***

Physical state	:	liquid
Colour	:	colourless
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

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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

Relative vapour density : No data available

### 9.2 Other information

#### **PT Level 2**

Explosives : Not explosive

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

Flammability (liquids) : Sustains combustion

Self-ignition : No data available

Evaporation rate : No data available

Miscibility with water : No data available

#### **PTCE/ACT/aPTT Bulb red**

Explosives : Not explosive

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

Self-ignition : No data available

Evaporation rate : No data available

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## SECTION 10: Stability and reactivity

### 10.1 Reactivity

No dangerous reaction known under conditions of normal use.

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### 10.2 Chemical stability

Stable under normal conditions.

### 10.3 Possibility of hazardous reactions

Hazardous reactions : Stable under recommended storage conditions.  
No hazards to be specially mentioned.

### 10.4 Conditions to avoid

No data available

### 10.5 Incompatible materials

No data available

### 10.6 Hazardous decomposition products

No data available

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## SECTION 11: Toxicological information

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

#### ***PT Level 2***

#### **Acute toxicity**

Not classified based on available information.

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

Not classified based on available information.

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

Not classified based on available information.

#### **Respiratory or skin sensitisation**

#### **Skin sensitisation**

Not classified based on available information.

#### **Respiratory sensitisation**

Not classified based on available information.

#### **Germ cell mutagenicity**

Not classified based on available information.

#### **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.

#### **Aspiration toxicity**

Not classified based on available information.

#### ***PTCE/ACT/aPTT Bulb red***



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### Acute toxicity

Not classified based on available information.

### Skin corrosion/irritation

Not classified based on available information.

### Serious eye damage/eye irritation

Not classified based on available information.

### Respiratory or skin sensitisation

#### Skin sensitisation

Not classified based on available information.

#### Respiratory sensitisation

Not classified based on available information.

#### Germ cell mutagenicity

Not classified based on available information.

#### 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.

#### 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.

## ***PT 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.

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#### **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**

#### ***PT Level 2***

No data available

#### ***PTCE/ACT/aPTT Bulb red***

No data available

### **12.2 Persistence and degradability**

#### ***PT Level 2***

No data available

#### ***PTCE/ACT/aPTT Bulb red***

No data available

### **12.3 Bioaccumulative potential**

#### ***PT Level 2***

No data available

#### ***PTCE/ACT/aPTT Bulb red***

No data available

### **12.4 Mobility in soil**

#### ***PT Level 2***

No data available

#### ***PTCE/ACT/aPTT Bulb red***

No data available

### **12.5 Results of PBT and vPvB assessment**

#### ***PT Level 2***

Not relevant

#### ***PTCE/ACT/aPTT Bulb red***

Not relevant

### **12.6 Endocrine disrupting properties**

##### **Product:**

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### **PT Level 2**

#### **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.

### **PTCE/ACT/aPTT Bulb red**

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**

#### **PT Level 2**

No data available

### **PTCE/ACT/aPTT Bulb red**

No data available

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## **SECTION 13: Disposal considerations**

### **13.1 Waste treatment methods**

Product : Can be disposed as waste water, when in compliance with local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.  
Do not re-use empty containers.

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## **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

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### 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

## SECTION 15: Regulatory information

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

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

Water hazard class (Germany) : WGK 1 slightly hazardous to water

#### **PT Level 2**

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations 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

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### 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.  Animal serum /-plasma /- hemolysate - different species, lyophilized Hepes, Hemisodium
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)

Not a hazardous substance or mixture.

### ***PTCE/ACT/aPTT Bulb red***

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations 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

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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

### 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 : On the inventory, or in compliance with the inventory
- DSL : All components of this product are on the Canadian DSL
- NZIoC : On the inventory, or in compliance with the inventory
- ENCS : On the inventory, or in compliance with the inventory
- ISHL : On the inventory, or in compliance with the inventory
- KECI : On the inventory, or in compliance with the inventory
- PICCS : On the inventory, or in compliance with the inventory
- IECSC : On the inventory, or in compliance with the inventory
- TCSI : On the inventory, or in compliance with the inventory
- TSCA : All substances listed as active on the 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)

Not a hazardous substance or mixture.

## 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 other abbreviations

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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

### 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