

1. Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

APC-PCI ELISA Kit (KIT 040) (for research use only)

Catalog No: KIT 040

1.2 Relevant, identified uses - and uses advised against (if any)

The APC-PCI ELISA Kit (KIT 040) is intended by BioPorto Diagnostics for the measurement of activated protein C – protein C inhibitor complex in human plasma. For Research Use Only. Not for use in diagnostic procedures.

1.3 Supplier of this MSDS



BioPorto Diagnostics A/S

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Title: QA & RA Manager

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1.4 Emergency phone number

Emergency telephone: 112 (Europe)

2. Hazards identification

2.1 Classification of mixture

There are no substances present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment and hence require reporting in this section.

2.2 Label elements

Mixture

With reference to subsection 2.1: NA.

2.3 Other hazards (if any) not resulting in classification

None known.

3. Composition/information on ingredients

The Kit contains the following components: 12x8 coated Microwells + Frame, Sample Diluent, 2 vials of freeze-dried APC-PCI Calibrator, 25x Wash Solution Conc., Biotinylated Protein C Antibody, HRP-Streptavidin, TMB Substrate and Stop Solution.

Mixtures

Component	Substance	Concentration (in kit component)	CAS Reg. #	EC #	Classification (kit component)
APC-PCI Calibrator	2-methyl-4-isothiazolin-3-one (as Proclin® 950)	0.1 % w/v	2682-20-4	220-239-6	NA
	Recombinant APC-PCI purified from human plasma	0.0000001 % w/v	-	-	NA
	Bovine Serum Albumine (bovine IgG)	-	-	-	NA. (US origin)
Sample Diluent	2-methyl-4-isothiazolin-3-one (as Proclin® 950)	0.1 % w/v	2682-20-4	220-239-6	NA
	Bovine Serum Albumine (bovine IgG)	-	-	-	NA. (US origin)
Biotinylated Protein C Antibody	2-methyl-4-isothiazolin-3-one (as Proclin® 950)	0.1 % w/v	2682-20-4	220-239-6	NA
	Bovine Serum Albumine (bovine IgG)	-	-	-	NA. (US origin)
25x Wash Solution Conc.	2-methyl-4-isothiazolin-3-one (as Proclin® 950)	0.1 % w/v	2682-20-4	220-239-6	NA
HRP- Streptavidin	Kathon (3:1 mixture of: 5-chloro-2-methyl-thiazol-3-one and 2-methylthiazol-3-one)	0.0001 % w/v	55965-84-9	-	NA
	Bovine Serum Albumine (bovine IgG)	-	-	-	NA. (US origin)
TMB Substrate	3,3',5,5' - tetramethylbenzidine	< 0.05 % w/v in H ₂ O	54827-17-7	259-364-6	NA
Stop Solution	Sulfuric Acid	0.5 mol/L	7664-93-9	231-639-5	NA

4. First aid measures**4.1 First aid measures**

After inhalation: Immediately remove the casualty from exposure and move to fresh air. If breathing stops, immediately apply mechanical ventilation and apply an oxygen mask if available. Arrange medical treatment.

After skin contact: Wash off with plenty of water. Remove contaminated clothing. If necessary arrange medical treatment.

After eye contact: Rinse out with plenty of water with the eyelids held wide open. Arrange medical treatment.

After ingestion: Immediately make casualty drink plenty of water. Immediately arrange medical treatment.

4.2 Important symptoms and effects, acute and delayed

If first aid measures are adhered to: No acute or delayed effects.

Otherwise: Irritation of skin, eyes.

4.3 Indication of immediate medical attention and special treatment

Other than described in subsection 4.1: At the discretion of medical staff, depending on the casualty's condition.

5. Fire-fighting measures**5.1 Suitable extinguishing media**

Use water spray, dry sand, carbon dioxide or foam depending on surrounding materials and equipment.

5.2 Special hazards arising from the substance or mixture

The mixtures are not flammable. Thermal decomposition of components is unlikely to result in any substances that are hazardous to health.

5.3 Advice for fire fighters

NA.

6. Accidental release measures**6.1 Personal precautions, protective equipment and emergency procedures**

As described in subsection 8.2.

Change any contaminated clothing.

6.2 Environmental precautions

Contain spillage. Prevent the mixtures from entering sewer systems.

6.3 Methods and material for containment and cleaning up

Take up with liquid-absorbant material. Forward for disposal. Clean up affected area with appropriate detergents.

6.4 References to other sections

References given when relevant.

7. Handling and storage**7.1 Precautions for safe handling**

General Good Laboratory Practice must be maintained.

The mixtures should not be present at the place of work in quantities above those required for carrying out the work.

7.2 Conditions for safe storage, including any incompatibilities

Adhere to storage recommendations and expiry date as indicated on product labels.

7.3 Specific end use(s)

The product is intended only for professional use and only for the uses described in subsection 1.2.

8. Exposure controls/personal protection

Data is for kit components and not for individual ingredients.

8.1 Control parameters

No limit values have been found on the mixtures or on the substances they contain. Refer to section 16 for any references.

8.2 Exposure controls

Adhere to local precautionary measures when handling potentially infectious samples.

General protective measures

NA when used as described in subsection 1.2.

Hygiene measures

Keep separated from food stuffs and beverages.

Respiratory protection

In case of unintentional release of mixtures in amounts where the possibility of aerosol formation exists:
Appropriate face mask.

Eye protection

Not required when handling as recommended.

Skin protection

Required. Wear laboratory coat and protective gloves. The glove material must be sufficient impermeable and resistant to the substance. Check the tightness before wear. Protect the skin.

Thermal hazards

None known.

9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

Where nothing else is stated, data apply to all components.

Parameter	Value	Method/Reference	Comments
a) Appearance	Clear to yellow or red solutions	Visual check	
b) Odor	Odorless	NA	
c) Odor threshold	NA	NA	No data available on the components. Not further investigated due to minimal relevance for these non-hazardous mixtures.
d) pH	Neutral, except Stop Solution: pH ~ 0.6	Glass electrode @ 25 °C	
e) Melting point/Freezing point	Data not available	NA	As c)
f) Initial boiling point and boiling range	Data not available	NA	As c)
g) Flash point	Data not available	NA	As c)
h) Evaporation rate	Data not available	NA	As c)
i) Flammability (solid, gas)	Data not available	NA	As c). Presumably not flammable.
j) Upper/lower flammability or explosive limits	Data not available	NA	As c) and i). Presumably not explosive.
k) Vapor pressure	Data not available	NA	As c)
l) Vapor density	Data not available	NA	As c)
m) Relative density	Data not available	NA	As c)
n) Solubility(ies)	Soluble in water	NA	As c)
o) Partition coefficient	Data not available	NA	As c)
p) Auto-ignition temperature	Data not available	NA	As c)
q) Decomposition temperature	Data not available	NA	As c)
r) Viscosity	Data not available	NA	As c)
s) Explosive properties	Data not available	NA	As c). Presumably not explosive.
t) Oxidizing properties	Data not available	NA	As c)

9.2 Other information

Please note that Stop Solution contains sulfuric acid (H₂SO₄) and has a corrosive effect.

10. Stability and reactivity

10.1 Reactivity

Not reactive.

10.2 Chemical stability

Stable. However, please note that: To obtain reliable results, the expiry date and storage recommendations as indicated on the product labels should be observed.

10.3 Possibility of hazardous reactions

No hazardous reactions known.

10.4 Conditions to avoid

None known.

10.5 Incompatible materials

None known.

10.6 Hazardous decomposition products

None known.

11. Toxicological information**11.1 Information on toxicological effects**

No toxicological information has been found on the kit components or their inherent substances in the relevant concentrations (see section 16 for references).

12. Ecological information

NA.

These mixtures are not classified as hazardous to human health or the environment.

No information on ecological hazards has been found on the kit components or the substances they contain in the relevant concentrations (see section 16 for references).

12.1 Toxicity: NA.**12.2 Persistence and degradability:** NA.**12.3 Bioaccumulative potential:** NA.**12.4 Mobility in soil:** NA.**12.5 Results of PBT and vPvB assessment:** NA.**12.6 Other adverse effects:** NA.**13. Disposal considerations**

National regulations for disposal must be adhered to for both disposal of packaging material and any remaining product.

When applicable, please refer to relevant sections (6, 11 and 12) of this MSDS for further guidance.

13.1 Waste treatment methods

No specific waste treatment methods required.

14. Transport information

No special transport regulations apply.

14.1 UN number: NA.**14.2 UN proper shipping name:** NA.**14.3 Transport hazard class(es):** NA.**14.4 Hazard group:** NA.**14.5 Environmental hazards:** NA.**14.6 Special precautions for user:** NA.**14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC code:** NA.

15. Regulatory information
15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

None known.

15.2 Chemical safety assessment

NA.

16. Other information

The classification procedure outlined in (EC) 1907/2006 as amended by Annex I of 453/2010 has been followed with appropriate references to 67/548/EC, 1999/45/EC and (EC) 1272/2008.

Information for sections 2, 3, 9, 10, 11 and 12 has been searched from the following sources:

1. ESIS (European Chemical Substances Information System).
2. The Danish Environmental Agency's Advisory Lists for Self Classification of Chemical Substances.
3. N-CLASS, ECOTOX, ChemIDPlus databases: The only information found has been on the substances **in their pure form**.

Information for subsection 8.1 has been searched for in 98/24/EC (risks related to chemical agents at work) and 2004/37/EC (risks related to exposure to carcinogens or mutagens at work) and in The Danish Working Environment Authority's (WEA) Guidance on Limit Values for Substances and Materials (C.0.1).

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Revision history

Version	Change	Date
01	New document	12.02.2009
02	Revised as a consequence of replacement of Bronidox with ProClin ®950. Smaller revisions acc. to (EU) No. 453/2010.	11.04.2011