

SAFETY DATA SHEET

according to ChemO 2015 - SR 813.11

APC-R C1 FV-L NEGATIVE CONTROL

55025R5

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

1.1 Product identifier

Trade name	APC-R C1 FV-L Negative Control
Article number	55025R5

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

Application of the substance / the mixture	Diagnostic reagent
	Kit component

1.3 Details of the supplier of the safety data sheet

Manufacturer/Supplier	Pentapharm AG Dornacherstrasse 112 CH- 4147 Aesch BL / Switzerland Phone +41 61 706 48 48 Fax +41 61 706 48 00
Further information obtainable from	pentapharm@pentapharm.com

1.4 Emergency telephone number

Tox Info Suisse : +41 44 251 51 51 (24h; 7 days a week)
Information desk: +41 44 251 66 66

* 2 Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008
The product is not classified, according to the CLP regulation.

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008

Void

Hazard pictograms

Void

Signal word

Void

Hazard statements

Void

2.3 Other hazards

Reagent 5 (55025R5) contains Human plasma (50 – 100%). Each donor unit used in the preparation of APC-R C1 FV-L Negative Control (R5) has been tested for antibodies against HIV Typ 1 and 2, Hepatitis C-virus antibodies, Treponema pallidum antibodies as well as Hepatitis B surface antigen and Hepatitis C genome by PCR.

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The tests used are all CE certified tests according to list A of the European Directive for IVD (98/79/EC) and are under supervision by the responsible European governmental authority. The plasmas were found to be negative on the test parameters.

However, since no test can completely rule out the presence of blood borne diseases these control plasmas have to be handled as potentially infectious material.

Results of PBT and vPvB assessment

PBT: According to current knowledge, the product contains no PBT substance.

vPvB: According to current knowledge, the product contains no vPvB substance.

Determination of endocrine-disrupting properties

Taking into account the current state of scientific knowledge, no data on endocrine disrupting properties of the product are available.

3 Composition/information on ingredients

3.1 Mixtures

Description

Mixture of substances listed below with nonhazardous additions.

Dangerous components

Void

SVHC

According to current knowledge no SVHC contained.

Additional information

For the wording of the listed hazard phrases refer to section 16.

4 First aid measures

4.1 Description of first aid measures

General information

No special measures required.

After inhalation

Remove person to fresh air and keep comfortable for breathing.

If experiencing respiratory symptoms: Call a POISON CENTER/doctor.

After skin contact

Wash with plenty of soap and water.

If skin irritation or rash occurs: Get medical advice/attention.

After eye contact

Rinse cautiously with water for several minutes.

Remove contact lenses, if present and easy to do. Continue rinsing.

If eye irritation persists: Get medical advice/attention.

After swallowing

Immediately call a POISON CENTER/doctor.

4.2 Most importance symptoms and effects, both acute and delayed

No further relevant information available.

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4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

5 Firefighting measures

5.1 Extinguishing media

Suitable extinguishing agents

CO₂, dry chemical powder, or appropriate foam.

5.2 Specific hazards arising from the substance or mixture

No further relevant information available.

5.3 Advice for firefighters

Protective equipment

Wear self-contained respiratory protective device.

Wear protective clothing to prevent contact with skin and eyes.

6 Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Avoid skin and eye contact and particle inhalation.

6.2 Environmental precautions

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

6.3 Methods and material for containment and cleaning up

Pick up mechanically.

Collect in suitable containers.

Clean the affected area carefully and ensure adequate ventilation.

Avoid dust formation.

6.4 Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

7 Handling and storage

7.1 Precautions for safe handling

Avoid skin and eye contact and particle inhalation.

Information about fire – and explosion protection

No special measures required.

7.2 Conditions for safe storage, including any incompatibilities

Storage:

Requirements to be met by storerooms and receptacles

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No special requirements.

Information about storage in one common storage facility

Not required.

Further information about storage conditions

Store in cool, dry conditions in well sealed receptacles.

Protect from heat and direct sunlight.

7.3 Specific end use(s)

No further relevant information available.

* 8 Exposure controls/personal protection

8.1 Control parameters

Ingredients with limit values that require monitoring at the workplace:

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

Additional information

The lists valid during the making were used as basis.

8.2 Exposure controls

Individual protection measures, such as personal protective equipment

General protective and hygienic measures:

The usual precautionary measures are to be adhered to when handling chemicals.

Ensure good ventilation/exhaustion at the workplace.

Keep away from foodstuffs, beverages and feed.

Avoid contact with the eyes and skin.

Wash hands before breaks and at the end of work.

Respiratory protection

Use suitable respiratory protective device in case of insufficient ventilation.

Respiratory protection must be compliant with the specifications of Directive 2016/425 and be in accordance with the EN standards resulting thereof.

Protection of hands



Protective gloves

Material of gloves

Protective gloves must be compliant with the specifications to Directive 2016/425 and be in accordance with the standards EN374. Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation. The selection of the suitable gloves does not only depend on the material, but also on

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further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material cannot be calculated in advance and has therefore to be checked prior to the application.

Eye/face protection



Safety glasses

Protective goggles must be compliant with the specifications of Directive 2016/425 and be in accordance with the standard EN166 (EU) or NIOSH (US).

Environmental exposure controls Do not allow product to reach ground water, water course or sewage system.

* 9 Physical and chemical properties

9.1 Information on basic physical and chemical properties

General Information	
Physical state:	Solid
Colour:	White
Odour:	Not determined.
Odour threshold:	Not determined.
Melting point/freezing point:	Not determined.
Boiling point or initial boiling point and boiling range:	Not determined.
Flammability:	Not determined.
Lower and upper explosion limit	
Lower:	Not determined.
Upper:	Not determined.
Flash point:	Not applicable.
Ignition temperature:	Not determined.
Decomposition temperature:	Not determined.
pH at 20 °C:	7.45 – 7.55
Viscosity	
Kinematic:	Not applicable.
Dynamic:	Not applicable.
Solubility	
Water:	Not determined.
Partition coefficient n-octanol/water (log value):	Not determined.

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Vapour pressure:	Not applicable.
Density and/or relative density	
Relative density:	Not determined.
Vapour density:	Not determined.
Particle characteristics:	Not determined.

9.2 Other information

Appearance	
Form:	Lyophilised solid
Important Information on protection of health, environment and on safety	
Auto-ignition temperature:	The product is not self-igniting.
Explosive properties:	The product does not present an explosion hazard.
Change in condition	
Softening point/range:	
Oxidising properties:	Not determined.
Evaporation rate:	Not applicable.

9.2.1 Information with regard to physical hazard classes

Explosives	Void
Flammable gases	Void
Aerosols	Void
Oxidising gases	Void
Gases under pressure	Void
Flammable liquids	Void
Flammable solids	Void
Self-reactive substances and mixtures	Void
Pyrophoric liquids	Void
Pyrophoric solids	Void
Self-heating substances and mixtures	Void
Substances and mixtures, which emit flammable gases in contact with water	Void
Oxidising liquids	Void
Oxidising solids	Void
Organic peroxides	Void
Corrosive to metals	Void
Desensitised explosives	Void

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10 Stability and reactivity

10.1 Reactivity

No further relevant information available.

10.2 Chemical stability

No information available.

Thermal decomposition / conditions to be avoided

No decomposition if used according to specifications.

10.3 Possibility of hazardous reactions

No dangerous reactions known.

10.4 Conditions to avoid

Heat may cause this product to decompose.

Avoid freezing.

10.5 Incompatible materials

No further relevant information available.

10.6 Hazardous decomposition products

Nature of decomposition products not known.

* 11 Toxicological information

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

Acute toxicity

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

LD/LC50 values relevant for classification

No further relevant information available.

Skin corrosion/irritation

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

Serious eye damage/irritation

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

Respiratory or skin sensitization

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

Germ cell mutagenicity

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

Carcinogenicity

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

Reproductive toxicity

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

STOT-single exposure

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

STOT-repeated exposure

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

Aspiration hazard

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

Other information

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11.2 Information on other hazards

Endocrine disrupting properties

Taking into account the current state of scientific knowledge, no data on endocrine disrupting properties of the product are available.

None of the ingredients is listed.

* **12 Ecological information**

12.1 Toxicity

Aquatic toxicity

No further relevant information available.

12.2 Persistence and degradability

No further relevant information available.

12.3 Bioaccumulative potential

No further relevant information available.

12.4 Mobility in soil

No further relevant information available.

12.5 Results of PBT and vPvB assessment

PBT

According to current knowledge, the product contains no PBT substance.

vPvB

According to current knowledge, the product contains no vPvB substance.

12.6 Endocrine disrupting properties

The product does not contain substances with endocrine disrupting properties.

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No further relevant information available.

13.1 Waste treatment methods

Disposal must be made according to official regulations.

Uncleaned packaging

Recommendation Disposal must be made according to official regulations.

14.1 UN-number or ID number

ADR/ADN, ADN, IMDG, IATA

ADR/ADN, ADN, IMDG, IATA

ADR/ADN, ADN, IMDG, IATA	
Class	Void

ADR/ADN, IMDG, IATA Void

Marine pollutant: Not applicable.

Not applicable.

to IMO instruments	Not applicable.
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Void

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* 15 Regulatory information

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

National regulations:

Special handling regulations (follow-up obligations) of the chemical legislation:

No additional regulations.

Ordinance on Air Pollution Control (OAPC; SR 814.318.142.1) Annex 1:

The provisions of the Air Pollution Control (OAPC; SR 814.318.142.1) Annex 1 are to be complied with.

Ordinance on Protection against Major Accidents (Major Accidents Ordinance, MAO; SR 814.012) Annex 1:

Volume threshold according to MAO in kg: without limitation

(Source: FOEN - List 2015 - Volume thresholds in accordance with the Major Accidents Ordinance / Volume Threshold Calculator)

Chemical Risk Reduction Ordinance (ORRChem; SR 814.81):

The product contains no substances subject to authorization according to Annex 1.17 in concentrations $\geq 0.1\%$ w/w

or above specific concentration limits (if $< 0.1\%$ w/w).

Chemical Risk Reduction Ordinance (ORRChem; SR 814.81):

The preparation or substances contained therein are not subject to any prohibition or restriction in accordance with Annexes 1 and 2.

Chemicals Ordinance (ChemO; SR 813.11):

The product contains no substances of very high concern according to Annex 3 in concentrations $\geq 0.1\%$ w/w.

Waterhazard class

Swiss Waterhazard class B (self classification)

OVOC (CH)

0.0%

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

* 16 Other information

All information and instructions provided in this Safety Data Sheet are based on the current state of scientific and technical knowledge at the date indicated on this Safety Data Sheet. Pentapharm AG shall not be held responsible for any defect in the product covered by this Safety Data Sheet, should the existence of such a defect not be detectable considering the current state of scientific and technical knowledge.

An asterisk (*) in the left hand margin indicates an amendment from the previous version.

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Abbreviations and acronyms

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

SVHC: Substances of Very High Concern

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.