

1. IDENTIFICATION OF THE PRODUCT AND COMPANY

- 1.1. Product name / Code : **APC Resistance Kit ~120 T** REF 5344510
APC Control Kit 2x1 ml REF 5344512
- 1.2. Recommended use : In-vitro diagnostic test kit
- 1.3. Manufacturer : Technoclone GmbH
 Brunnerstr. 59/5
 A-1235 Vienna / AUSTRIA
 Tel. + 43 1 86373 - 0
 Fax + 43 1 86373 - 44
- 1.4. Emergency Phone : +43 1 86373 -10

2. COMPOSITION AND INFORMATION ON INGREDIENTS

- 2.1. Chemical characterization : **APC Resistance Kit ~120 T** REF 5344510
 The kit consists of 5 reagents

Reagent	Label	Composition	Appearance Color	Physical state	Odor	pH
R1	APC/RVV-V (+APC) Reagent	APC, RVV-V, Polybrene, Hepes, BSA	white	lyophilisate	None	7.4-7.6
R2	RVV-V (-APC) Reagent	RVV-V, Polyberen Hepes, BSA	white	lyophilisate	None	7.4-7.6
R3	PTA Reagent	Prothrombin Activator, EDTA, Hepes, BSA	white	lyophilisate	None	7.4-7.6
R4	Dilution Plasma	Human Plasma, processed	beige	lyophilisate	None	7.4-7.6
C1	FV-L Negative Control	Pooled normal human plasma from wild-type blood donors, processed	beige	lyophilisate	None	7.4-7.6*
C2	FV-L Heterozygous Control	Pooled normal human plasma from wild-type blood donors, processed	beige	lyophilisate	None	7.4-7.6*

* after reconstitution with deionized water

All reagents are lyophilized mixtures of several general purpose and analyte specific reagents to be reconstituted with deionized water. Except for the hazardous ingredients described under 2.2. none of the ingredients are classified as dangerous acc. to the European Community Directive 93/112/EC amended 91/155/EC.

- APC Control Kit 2x1 ml** REF 5344512
 The kit consists of 2 control reagents

Reagent	Label	Composition	Appearance Color	Physical state	Odor	pH
C1	FV-L Negative Control	Pooled normal human plasma from wild-type blood donors, processed	beige	lyophilisate	None	7.4-7.6*
C2	FV-L Heterozygous Control	Pooled normal human plasma from wild-type blood donors, processed	beige	lyophilisate	None	7.4-7.6*

* after reconstitution with deionized water

The controls consists of processed and lyophilized human plasma. None of the ingredients are classified as dangerous acc. to the European Community Directive 93/112/EC amended 91/155/EC.

2.2. <u>Hazardous ingredients</u>	<u>CAS No</u>	<u>Concentration</u>	<u>EU Classification</u>
Reagents 1,2:			
Hexadimethrine Bromide	28728-55-4	< 0.1 %	Xn R 20/21/22 S 26
Reagent 1:			
Human activated Protein C (APC)	--	< 0.1 %	--
Reagent 4:			
Human Plasma (FNP)	--	--	--
Controls 1,2:			
Human Plasma (FNP)	--	--	--

3. HAZARD IDENTIFICATION

Reagents 1,2:

Reagents containing hexadimethrine bromide in a lower concentration than 0.1 % are not classified as dangerous acc. to the European Community Directive 93/112/EC amended 91/155/EC.

Reagents 1,4 and Controls 1,2:

Reagents and Control solutions containing human plasma* or human plasma derived material. They should be handled with care, observing the precautions recommended for bio-hazardous material.

* The human plasma is tested on antibodies against HIV Typ 1 and 2, Hepatitis C-virus, Treponema pallidum and Hepatitis B surface antigen. Hepatitis C was tested by PCR screen. The plasma was found to be negative. As complete absence of infectious agents can never be assured, all materials derived from human or bovine tissue or body fluids should always be handled with care, observing the precautions recommended for bio-hazardous material.

Emergency overview: general rules for handling biological material have to be followed

4. FIRST AID MEASURES

4.1. Skin Contact	:	Rinse with water, and wipe with skin disinfectant.
4.2. Eye Contact	:	Flush eyes immediately with water, if persistent irritation occurs, seek medical advice.
4.3. Inhalation	:	Seek medical advice immediately.
4.4. Ingestion	:	Wash out mouth with water, seek medical advice immediately.
4.5. Other first aid information	:	In case of injury and contamination with human plasma material it is strongly recommended to consult a physician.

5. FIRE FIGHTING MEASURES

5.1. Extinguishing media	:	Carbon dioxide, foam, dry powder, water
5.2. Unsuitable extinguishing media	:	None known
5.3. Unusual fire-fighting hazards	:	The products of combustion are toxic
5.4. Special fire-fighting procedure	:	None known
5.4. Other recommendations	:	No special precautions and measures necessary

6. ACCIDENTAL RELEASE MEASURES

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|------|------------------------------------|---|--|
| 6.1. | Personal precautions | : | Avoid eye contact. |
| 6.2. | Precautions to protect environment | : | Keep away from drains and ground water. |
| 6.3. | Cleanup procedures | : | Avoid dust formation. Sweep up and hold in suitable containers for appropriate waste disposal. |

7. HANDLING AND STORAGE

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|------|----------------------|---|--|
| 7.1. | Handling precautions | : | In the case of accident avoid skin and eye contact with the released material. Wear gloves and protect yourself from injury by broken glass. No special measures required. |
| 7.2. | Storage precautions | : | Refrigerator +2...8°C |
| 7.3. | Other information | : | Lyophilized reagents are hygroscopic. Keep vials tightly closed. |

8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

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|------|-------------------------------|---|--|
| 8.1. | Exposure controls | : | See 7.1. |
| 8.2. | Engineering control measures | : | No special control measures necessary. |
| 8.3. | Personal protective equipment | | |
| | Respiratory protection | : | No respiratory protection is required when usual industrial hygiene measures are observed. |
| | Hand protection | : | Gloves |
| | Eye protection | : | Safety glasses |
| | Skin protection | : | Additional protective equipment is normally not required |
| | Other | : | -- |

9. PHYSICAL AND CHEMICAL PROPERTIES

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|------|----------------------------|---|-----------------------------|
| 9.1. | Appearance /Colour | : | See 2.1. |
| | Physical state | : | See 2.1. |
| | Odor | : | See 2.1. |
| 9.2. | Safety related information | | |
| | pH | : | See 2.1. |
| | Other parameters | : | Not available or determined |

10. STABILITY AND REACTIVITY

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|-------|----------------------------------|---|-----------------------------------|
| 10.1. | Conditions to avoid | : | Temperatures above 25°C, freezing |
| 10.2. | Materials to avoid | : | None known |
| 10.3. | Hazardous decomposition products | : | None known |

11. TOXICOLOGICAL INFORMATION

11.1. Acute Toxicity

Hexadimethrine bromide : LD₁₀ >1000 mg/kg (mouse/oral)
LD₅₀ 20 mg/kg (rat, i.v.)
LD₅₀ 30 mg/kg (rat, i.v.)

12. ECOLOGICAL INFORMATION

12.1. Ecotoxicity : No information available

13. DISPOSAL CONSIDERATIONS

13.1. Product disposal : Incineration according to local and national legislation.
13.2. Packaging disposal : Dispose of in a manner in accordance with local and national regulations.

14. TRANSPORT INFORMATION

14.1. UN. No. : Not applicable
14.2. Road and rail transport (ADR/RID) : Not applicable
14.3. Air transport (ICAO/IATA-DGR) : Not applicable
14.4. Sea transport (IMO/IMDG) : Not applicable
14.5. Inland navigation (AND(ADNR)) : Not applicable
14.6. Other information : None

15. REGULATORY INFORMATION

15.1. Not classified as dangerous acc. to European Community Directive 93/21/EEC
15.2. National legislation:
For further product information, we recommend consideration of the corresponding appropriate National Legislation.

16. OTHER INFORMATION

This Safety Data Sheet complies with the European Community Directive 93/112/EC amended 91/155/EC.

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. Technoclone GmbH 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.

It characterizes the product with regard to the appropriate safety precautions. It does not represent a guarantee of the properties of the product.