

Safety Data Sheet

APC-R Kit



SDS No. 0A00.01

p 1/7 EN

Temp.: TFD366.01
Art. 01 to D00068

ACCORDING TO EC-REGULATIONS 1907/2006 (REACH), 1272/2008 (CLP) & 2020/878

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Product Name/Reference No.	APC-R Kit	120 T.	REF 5344510
	APC-R Kit	40 T.	REF 5344515
Product Components	Component R1	APC/RVV-V (+APC)	3 x 2 mL (120 T.) 1 x 2 mL (40 T.)
	Component R2	RVV-V (-APC)	3 x 2 mL (120 T.) 1 x 2 mL (40 T.)
	Component R3	PTA Reagent	3 x 4 mL (120 T.) 1 x 4 mL (40 T.)
	Component R4	Dilution Plasma	3 x 2 mL (120 T.) 1 x 2 mL (40 T.)
	Component C1	FV-L negative control	1 x 1 mL
	Component C2	FV-L heterozygous control	1 x 1 mL

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

Component R1	For professional users only
Component R2	Not known.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Company Identification	Technoclone Herstellung von Diagnostika und Arzneimitteln GmbH
Address of Manufacturer	Brunner Strasse 67 1230 Vienna Austria
Postal code	1230
Telephone:	+43 1 86373-0
Fax	+43 1 86373-44
E-mail	products@technoclone.com
Office hours	8:00 – 16:00

1.4 Emergency telephone number

Emergency Phone No.	+43 1 86373-0
Contact	products@technoclone.com
National response center	
Address	NHS Direct
Emergency Phone No.	+44 111

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

		Regulation (EC) No. 1272/2008 (CLP)
Component R1	APC/RVV-V (+APC)	Not classified as dangerous for supply/use
Component R2	RVV-V (-APC)	Not classified as dangerous for supply/use
Component R3	PTA Reagent	Classified as acute tox. Cat. 4
Component R4	Dilution Plasma	Not classified as dangerous for supply/use
Component C1	FV-L negative control	Not classified as dangerous for supply/use
Component C2	FV-L heterozygous control	Not classified as dangerous for supply/use

2.2 Label elements

Product Name
Hazard Pictogram(s)

According to Regulation (EC) No. 1272/2008 (CLP)
APC-R Kit, component R3, PTA Reagent



GHS 07



GHS 08

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Signal Word(s)	Warning
Hazard Statement(s)	H302 Harmful if swallowed. H332 Harmful if inhaled. H373 May cause damage to the respiratory system through prolonged or repeated exposure. Route of exposure: Inhalation
Precautionary Statement(s)	P260 Do not breathe dust. P264 Wash hands thoroughly after handling P310 Immediately call a poison center/doctor

2.3 Other hazards

None known.

2.4 Additional Information

Component R1	APC/RVV-V (+APC)	Contains animal derived material – potentially biohazardous
Component R2	RVV-V (-APC)	Contains animal derived material – potentially biohazardous
Component R3	PTA Reagent	Contains animal derived material – potentially biohazardous
Component R4	Dilution Plasma	Contains human derived material - potentially biohazardous
Component C1	FV-L negative control	Contains human derived material - potentially biohazardous
Component C2	FV-L heterozygous control	Contains human derived material - potentially biohazardous

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Not applicable.

3.2 Mixtures

Component R3 PTA Reagent

HAZARDOUS INGREDIENT(S)	CAS No.	EC No. / REACH Registration No.	%W/W	Hazard Statement(s)	Hazard Pictogram(s)
Disodium dihydrogen ethylenediaminetetraacetate	139-33-3	205-358-3	≤ 50	Acute Tox. 4 H332 STOT RE 2 H373	GHS08 GHS07

HAZARDOUS INGREDIENT(S)	CAS No.	Specific Concentration Limit	M-factor	ATE
Disodium dihydrogen ethylenediaminetetraacetate	139-33-3	n.a.	n.a.	Acute Tox. 4 (H332) : 0.000

Contains no non-classified vPvB substances or substances with a Union workplace exposure limit.
For full text of H/P Statements see section 16.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

Inhalation	If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.
Skin Contact	Wash skin with water.
Eye Contact	Flush eyes with water for at least 15 minutes.
Ingestion	Wash out mouth with water.

4.2 Most important symptoms and effects, both acute and delayed

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None anticipated. Treat symptomatically.

4.3 Indication of any immediate medical attention and special treatment needed

Unlikely to be required but if necessary treat symptomatically.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable Extinguishing media As appropriate for surrounding fire.
Unsuitable extinguishing media None.

5.2 Special hazards arising from the substance or mixture

None anticipated. Heating may cause decomposition.

5.3 Advice for firefighters

As appropriate for surrounding fire.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Provide adequate ventilation. Wear suitable gloves if prolonged skin contact is likely.

6.2 Environmental precautions

Do not release large quantities into the surface water or into drains.

6.3 Methods and material for containment and cleaning up

Sweep spilled substances into containers if appropriate moisten first to prevent dusting.

6.4 Reference to other sections

See Also Section 8, 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Not known.

7.2 Conditions for safe storage, including any incompatibilities

Storage temperature 2°C to 8°C
Storage life Stable under normal conditions.
Incompatible materials None known.

7.3 Specific end use(s)

In vitro diagnostic use

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

8.1.1 Occupational Exposure Limits No Occupational Exposure Limit assigned.

8.2 Exposure controls

8.2.1. Appropriate engineering controls Ensure adequate ventilation.

8.2.2. Personal protection equipment

Eye Protection Wear eye protection with side protection (EN166).
Skin protection Gloves recommended
Respiratory protection Normally no personal respiratory protection is necessary.
Thermal hazards None known.

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8.2.3. Environmental Exposure Controls Do not release large quantities into the surface water or into drains.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Physical state – all components	solid
Colour – all components	Without colour
Odour all components	odourless
Melting point/freezing point	Not known.
Boiling point or initial boiling point and boiling range	Not applicable.
Flammability	Not known.
Lower and upper explosion limit	Not known.
Flash Point	Not applicable.
Auto-ignition temperature	Not known.
Decomposition Temperature	Not known.
pH	Not known.
Kinematic Viscosity	Not known.
Solubility	Solubility (Water) : readily miscible. Solubility (Other) : Not known
Partition coefficient n-octanol/water (log value)	Not known.
Vapour pressure	Not known.
Density and/or relative density	Not known.
Relative vapour density	Not known.
Particle characteristics	Not known.

9.2 Other information

None.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

None anticipated.

10.2 Chemical Stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

No hazardous reactions known if used for its intended purpose.

10.4 Conditions to avoid

None anticipated.

10.5 Incompatible materials

Not known.

10.6 Hazardous decomposition products

No hazardous decomposition products known.

SECTION 11: TOXICOLOGICAL INFORMATION

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

Acute toxicity - Ingestion	Low acute toxicity
Acute toxicity - Skin Contact	Low acute toxicity
Acute toxicity - Inhalation	Low acute toxicity
Skin corrosion/irritation	Non-irritant
Serious eye damage/irritation	Non-irritant
Skin sensitization data	Not classified
Respiratory sensitization data	Not classified

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Germ cell mutagenicity	There is no evidence of mutagenic potential.
Carcinogenicity	No evidence of carcinogenicity.
Reproductive toxicity	Not classified
Lactation	Not classified
STOT - single exposure	Not classified
STOT - repeated exposure	Not classified
Aspiration hazard	Not classified

11.2 Information on other hazards

Not known.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Toxicity - Aquatic invertebrates	Low toxicity to invertebrates.
Toxicity - Fish	Low toxicity to fish.
Toxicity - Algae	Low toxicity to algae.
Toxicity - Sediment Compartment	Not classified.
Toxicity - Terrestrial Compartment	Not classified.

12.2 Persistence and degradability

Not known.

12.3 Bioaccumulative potential

Not known.

12.4 Mobility in soil

Not known.

12.5 Results of PBT and vPvB assessment

Not known.

12.6 Endocrine disrupting properties

None known.

12.7 Other adverse effects

Not known.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Dispose at suitable refuse site.

13.2 Additional Information

No special precautions are required for this product.

SECTION 14: TRANSPORT INFORMATION

Not classified as hazardous for transport.

14.1 UN number or ID number

Not applicable

14.2 UN proper shipping name

Not applicable

14.3 Transport hazard class(es)

Not applicable

14.4 Packing group

Not applicable

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14.5 Environmental hazards

Not classified as a Marine Pollutant.

14.6 Special precautions for user

Not known

14.7 Maritime transport in bulk according to IMO instruments

Not known

SECTION 15: REGULATORY INFORMATION

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

European Regulations - Authorisations and/or Restrictions On Use

Candidate List of Substances of Very High Concern for Authorisation	Not listed
REACH: ANNEX XIV list of substances subject to authorisation	Not listed
REACH: Annex XVII Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles	Disodium dihydrogen ethylenediaminetetraacetate (CAS 139-33-3)
Community Rolling Action Plan (CoRAP)	Not listed
Regulation (EC) N° 2019/1021 of the European Parliament and of the Council on persistent organic pollutants	Not listed
Regulation (EC) N° 1005/2009 on substances that deplete the ozone layer	Not listed
Regulation (EU) N° 649/2012 of the European Parliament and of the Council concerning the export and import of hazardous chemicals	Not listed

National regulations

Other Not known.

15.2 Chemical Safety Assessment

A REACH chemical safety assessment has not been carried out.

SECTION 16: OTHER INFORMATION

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Date of Revision 30.05.2023

LEGEND

Hazard Pictogram(s)	GHS07: Exclamation mark GHS08: Health hazard
Hazard classification	Acute Tox. 4 : Acute toxicity, Category 4 STOT RE 2 : Specific target organ toxicity — repeated exposure, Category 2
Hazard Statement(s)	H332: Harmful if inhaled. H373: May cause damage to organs through prolonged or repeated exposure.
Precautionary Statement(s)	None.

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Acronyms

ATE : Acute Toxicity Estimate
CAS : Chemical Abstracts Service
CLP : Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
DNEL : Derived No Effect Level
EC : European Community
EINECS : European Inventory of Existing Commercial Chemical Substances
LTEL : Long term exposure limit
PBT : Persistent, Bioaccumulative and Toxic
PNEC : Predicted No Effect Concentration
REACH : Registration, Evaluation, Authorisation and Restriction of Chemicals
STEL : Short term exposure limit
STOT : Specific Target Organ Toxicity
vPvB : very Persistent and very Bioaccumulative

Key literature references and sources for data used to compile the SDS

Regulation (EC) No. 1272/2008 (CLP)

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