

Safety Data Sheet - SDS

according to Regulation (EC) No.1907/2006


PCA Ratio in Factor V Depleted Plasma

1. IDENTIFICATION OF SUBSTANCE / PREPARATION AND COMPANY.

1.1 Product Identifiers.

Product name : PCA Ratio in Factor V Depleted Plasma.
Product codes : APCV380.
Index Number : Not indexed in regulation (EC) No.1272/2008.
REACH No. : Not required due to exemption from registration (below the annual tonnage for downstream user).
CAS Number : Not indexed.

1.2 Identified uses: To diagnose patients with Activated Protein C Resistance.

1.3 Company : **Diagnostic Reagents Ltd.**

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 Thame,
 Oxon, OX9 3NY,
 UK.

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Fax : +44(0)1844 216162
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1.4 Emergency Tel: **+44(0)1844 212426** (Monday to Friday, 09.00 to 17.00)

2. HAZARDS IDENTIFICATION.

2.1 Classification of the substance or mixture according to regulation (EC) No 1272/2008 (EU-GHS/CLP).

Not a dangerous substance according to GHS.

2.2 Label Elements :

Labelling according to Regulation (EC) No 1272/2008 (CLP).

The product does not need to be labelled in accordance with EC directives or respective national laws.

2.3 Other hazards

PCA Ratio Kit in FV depleted plasma reagents contain ingredients derived from bovine brain. All materials have been processed from animals passed fit for human consumption, it is however recommended that standard precautions are taken, as for any potentially infectious material. See section 16 for further details. The Kit also contains lyophilised Human Plasma (APCC400 & IDHP191) the SDS for which can be found at the end of this document.

3. COMPOSITION / INFORMATION ON INGREDIENTS.

3.1 N/A.

3.2 Mixtures.

Synonyms : Activated Protein C Resistance test.

Component	Classification	Concentration
Bovine Phospholipid CAS No. 93384-34-0 EC No. N/A	Not classified.	≤4%
Micronised Silica CAS No. 7631-86-9 EC No. 310-194-1	Not classified.	≤1%
Agkistrodon contortrix contortix CAS No. N/A EC No. N/A	Not classified.	≤0.001%

4. FIRST AID MEASURES.**4.1 Description of first aid measures.****General Advice.**

Consult a physician. Show this SDS to the doctor in attendance.

If inhaled.

Move the person into fresh air. If not breathing give artificial respiration. Consult a physician.

In case of skin contact.

Wash the area with soap and plenty of water. If a reaction occurs consult a physician.

In case of eye contact.

Rinse the eye thoroughly with plenty of water for at least 15 minutes and consult a physician.

If swallowed.

Rinse mouth with water. Never give anything by mouth to an unconscious person. Consult a physician.

4.2 Most important symptoms and effects, both acute and delayed.

PCA Ratio Kit reagents are used in blood clotting assays. There are currently no chemical, physical or toxicological properties that have been thoroughly investigated.

4.3 Indication of any immediate medical attention and special treatment needed.

No data available.

5. FIRE FIGHTING MEASURES.**5.1 Extinguishing media.****Suitable extinguishing media.**

Water Spray, alcohol-resistant foam, dry chemical or Carbon dioxide.

5.2 Special Hazards arising from the substance or mixture.

Nature of decomposition products not known.

5.3 Advice for firefighters.

When entering any fire, please ensure the correct protective clothing and self contained breathing apparatus are worn.

5.4 Further information.

No data available.

6. ACCIDENTAL RELEASE MEASURES.**6.1 Personal Precautions, protective equipment and emergency procedures.**

Use personal protective equipment. Avoid dust formation. Avoid inhaling dust. Ensure adequate ventilation. Evacuate personnel to a safe area if necessary.

6.2 Environmental precautions.

Do not allow product to enter the drains.

6.3 Methods and materials for containment and cleaning up.

Sweep up and shovel, or vacuum, creating as little dust as possible. Once contained, hold in suitable, closed container for disposal.

6.4 Reference to other sections.

For disposal see section 13.

7. HANDLING AND STORAGE.

- 7.1 Precautions for safe handling.**
Avoid skin and eye contact. Avoid dust and aerosol formation. Provide appropriate exhaust ventilation at places where dust is formed.
- 7.2 Conditions for safe storage, including any incompatibilities.**
Store according to manufacturers instruction in a cool place. Keep containers tightly closed when storing. The recommended storage temperature is 2-8°C.
- 7.3 Specific end use(s).**
Apart from those uses mentioned in section 1.2 no other specific uses are stipulated.

8. EXPOSURE CONTROL / PERSONAL PROTECTION.**8.1 Control Parameters.**

Components with workplace control parameters.
Contains no substances with workplace exposure limits (WEL).

8.2 Exposure controls.

Appropriate engineering controls.
Handle in accordance with good laboratory practice (GLP). Wash hands before breaks and immediately after handling this product.

8.3 Personal protective equipment.**Eye/face protection.**

A face shield or safety glasses. Use equipment tested and approved by government standards such as EN 166 (EU) or NIOSH (US).

Skin protection.

Handle with gloves. Gloves should be thoroughly checked before use. Use correct glove removal technique to avoid skin contact with this product. Dispose of any used gloves in accordance with applicable laws and Good Laboratory Practice (GLP).

Wash and dry hands thoroughly after use.

Protective gloves should adhere to the specifications detailed in EU directive 89/686/EEC and the derived standard EN374. A experienced Safety Officer should conduct a thorough assessment of any procedure using this product before proceeding.

Body Protection.

Wear impervious protective clothing, including boots, gloves, lab coat, apron or overalls as appropriate, to prevent skin contact. The extend of the protective equipment must be selected according to the concentration and the amount of substance being used.

Respiratory protection.

For nuisance exposures use type N95 (US) or type P1 (EU EN143). Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

9. PHYSICAL AND CHEMICAL PROPERTIES.**9.1 Information on basic chemical and physical properties.**

a) Physical state:	Powder, white, lyophilised.	m) Relative density:	Not available.
b) Odour:	Odourless.	n) Water solubility:	Complete in water
c) pH:	7.3.	o) Partition coefficient:	Not available.
d) Melting/freezing point	Not available.	p) Auto ignition temp.	Not available.
e) Boiling point/range:	Not available.	q) Decomposition temperature	Not available.
g) Flash point:	Not available.	r) Viscosity	Not available.
h) Evaporation rate:	Not available.		
i) Flammability:	Not available.		
j) Explosive properties:	Not available.		
k) Vapour pressure	Not available.		
l) Vapour density	Not available.		
Other information:	Not available.		

10. STABILITY AND REACTIVITY.

- 10.1 Reactivity**
No data available
- 10.2 Chemical Stability**
Stable under recommended storage conditions.
- 10.3 Possibility of hazardous reactions**
No data available.
- 10.4 Conditions to avoid:**
Temperatures above 25°C.
- 10.5 Materials to avoid:**
Strong oxidising agents..
- 10.6 Hazardous decomposition products**
Other decomposition products - no data available.

11. TOXICOLOGICAL INFORMATION.**11.1 Information on toxicological effects****Acute toxicity:**

LD50 (Agkistrodon contortrix contortrix venom), Intravenous, Mouse - 10.9mg/kg.

LD50 (Agkistrodon contortrix contortrix venom), Subcutaneous, Mouse - 25.6mg/kg.

LD50 (Agkistrodon contortrix contortrix venom), Intraperitoneal, Mouse - 10.9mg/kg.

Skin corrosion/irritation

No data available.

Serious eye damage/irritation.

No data available.

Respiratory or skin sensitisation.

No data available.

Germ cell mutagenicity.

No Data Available.

Carcinogenicity.

IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

Reproductive toxicity.

No data available.

Specific target organ toxicity - single exposure.

No data available.

Specific target organ toxicity - repeated exposure.

No data available.

Aspiration hazard.

No data available.

Potential health effects.

Inhalation	May be harmful if inhaled. May cause respiratory tract irritation.
Ingestion	May be harmful if swallowed.
Skin	May cause skin irritation.
Eyes	May cause eye irritation.

Signs and Symptoms of Exposure.

PCA Ratio Kit reagents are used in blood clotting assays. There are currently no chemical, physical and toxicological properties that have been thoroughly investigated.

Additional information.

RTECS: N/A

12. ECOLOGICAL INFORMATION

- 12.1 Toxicity.**
No data available.
- 12.2 Persistence/Biodegradability.**
No data available.
- 12.3 Bioaccumulation potential.**
No data available.
- 12.4 Mobility in soil.**
No data available.
- 12.5 Other adverse effects.**
No data available.

13. DISPOSAL CONSIDERATIONS.**13.1 Waste Treatment methods.****Product.**

Offer surplus and non-recyclable solutions to a licensed disposal company. Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator with an afterburner and scrubber.

Contaminated Packaging.

Dispose of as an unused product.

14. TRANSPORT INFORMATION.**RID/ADR:**

UK Road Class:	-	UK Road Packaging Group:	-
UN No. (Road):	-	RID Class No.	-
Proper Shipping Name:	Not dangerous goods.	RID Pack Group:	-
Hazchem Code:	-	CEPIC TEC-R No.	-
ADR Class No.	-	ADR Class:	-
ADR Pack Group:	-	ADR Label No:	-

IMDG:

IMDG Class:	-	IMDG Pack Group:	-
UN No. (Sea):	-	MFAG:	-
Proper Shipping Name:	Not dangerous goods.	IMDG Page No:	-
EMS:	-		
Marine pollutant:	-		

IATA:

Air Class:	-	Air Pack Group:	-
UN Air No.	-		
Proper Shipping Name:	Not dangerous goods.		

- 14.6 Special precautions for user:**
No data available.

15. REGULATORY INFORMATION.

This safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006.

- 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture.**
No data available.
- 15.2 Chemical Safety Assessment.**
A chemical safety assessment has not been carried out for this product.

16. OTHER INFORMATION**Further Information**

Cattle used in the production of Bovine Phospholipid have passed both ante and post mortem inspection and have been passed fit for human consumption. Normal precautions should still be observed for potentially infectious material. All the above information is based on current knowledge at the time of publication and follows stipulated regulations. Diagnostic Reagents Ltd is not responsible for any errors or lack of information given in the above literature. The information contained in this SDS does not constitute an assessment of work place risks and is intended only as a guide to the appropriate precautionary handling of a material by a trained person using this product. The customer should undertake a formal COSHH assessment which should ensure that employees are aware of the hazards / precautions detailed in this SDS. The COSHH assessment should ensure that the recommended safety equipment is available and where applicable, that the exposure limits are not being exceeded. Diagnostic Reagents Ltd will not therefore be responsible for damages resulting from use of or reliance upon this information.

Safety Data Sheet - SDS

according to Regulation (EC) No.1907/2006

Human Plasma

1. IDENTIFICATION OF SUBSTANCE / PREPARATION AND COMPANY.

1.1 Product Identifiers.

Product names/codes: APC Resistance Control Plasma APCC400
Factor V Depleted Plasma - 2 mL. IDHP191

Index Number : Not indexed in regulation (EC) No.1272/2008.
REACH No. : Not required due to exemption from registration (below the annual tonnage for downstream user).
CAS Number : Not indexed.

1.2 Identified uses: Used in blood coagulation for reference and control of *In vitro* Diagnostics (IVDs).

1.3 Company : **Diagnostic Reagents Ltd.**



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2. HAZARDS IDENTIFICATION.

2.1 Classification of the substance or mixture according to regulation (EC) No 1272/2008 (EC-GHS/CLP).

Not a dangerous substance according to GHS.

2.2 Label Elements :

Labelling according to Regulation (EC) No 1272/2008 (CLP).

The product does not need to be labelled in accordance with EC directives or respective national laws.

2.3 Other hazards

Potential biohazard, contains human source material. Handle as though capable of transmitting infectious agents. See section 16 for further information.

3. COMPOSITION / INFORMATION ON INGREDIENTS.

3.1 Substances.

Synonyms : Citrated Human Plasma

Component	Classification	Concentration
Human Citrated Plasma	Not classified.	≥99%
CAS No. N/A		
EC No. N/A		

4. FIRST AID MEASURES.**4.1 Description of first aid measures.****General Advice.**

The Product is miscible in water.

If inhaled.

Move the person into fresh air. If not breathing give artificial respiration.

In case of skin contact.

Wash the area with soap and plenty of water.

In case of eye contact.

Rinse the eye thoroughly as a precaution.

If swallowed.

Rinse mouth with water. Never give anything by mouth to an unconscious person. Consult a physician.

4.2 Most important symptoms and effects, both acute and delayed.

Human plasma is considered non hazardous, however all known symptoms and effects are described in the labelling (section 2.2) and/or in section 11.

4.3 Indication of any immediate medical attention and special treatment needed.

No data available.

5. FIRE FIGHTING MEASURES.**5.1 Extinguishing media.****Suitable extinguishing media.**

Water Spray, alcohol-resistant foam, dry chemical or Carbon dioxide.

5.2 Special Hazards arising from the substance or mixture.

Nature of decomposition products not known.

5.3 Advice for firefighters.

When entering any fire, please ensure the correct protective clothing and self contained breathing apparatus are worn.

5.4 Further information.

No data available.

6. ACCIDENTAL RELEASE MEASURES.**6.1 Personal Precautions, protective equipment and emergency procedures.**

Use personal protective equipment. Avoid dust formation. Avoid inhaling dust. Ensure adequate ventilation. For personal protection see section 8.

6.2 Environmental precautions.

Do not allow product to enter the drains.

6.3 Methods and materials for containment and cleaning up.

Keep in suitable closed containers ready for disposal by incineration.

6.4 Reference to other sections.

For disposal see section 13.

7. HANDLING AND STORAGE.**7.1 Precautions for safe handling.**

Avoid skin and eye contact. Avoid dust and aerosol formation. The product should be treated as potentially infectious.

7.2 Conditions for safe storage, including any incompatibilities.

Store according to manufacturers instruction in a cool place. Keep container tightly closed when storing. Store under inert gas. Moisture sensitive. The recommended storage temperature is -20°C.

7.3 Specific end use(s).

Apart from those uses mentioned in section 1.2 no other specific uses are stipulated.

8. EXPOSURE CONTROL / PERSONAL PROTECTION.**8.1 Control Parameters.****Components with workplace control parameters.**

Contains no substances with occupational exposure limits.

8.2 Exposure controls.**Appropriate engineering controls.**

Handle in accordance with good laboratory practice. Wash hands before breaks and immediately after handling this product.

8.3 Personal protective equipment.**Eye/face protection.**

Eye protection is not necessary, however if required, use equipment tested and approved by government standards such as EN 166 (EU) or NIOSH (US).

Skin protection.

Handle with gloves. Gloves should be thoroughly checked before use. Use correct glove removal technique to avoid skin contact with this product. Dispose of any used gloves in accordance with applicable laws and Good Laboratory Practice (GLP).

Wash and dry hands thoroughly after use.

Protective gloves should adhere to the specifications detailed in EU directive 89/686/EEC and the derived standard EN374. A experienced Safety Officer should conduct a thorough assessment of any

Body Protection.

Wear impervious protective clothing, in this case a laboratory coat will suffice.

Respiratory protection.

Not required. For nuisance exposures use type P95 (US) or type P1 (EU EN143). Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

9. PHYSICAL AND CHEMICAL PROPERTIES.**9.1 Information on basic chemical and physical properties.**

a) Physical state:	Lyophilised cake, Straw colour.	m) Relative density:	Not available.
b) Odour:	Not available.	n) Water solubility:	Miscible with water.
c) pH:	Not available.	o) Partition coefficient:	Not available.
d) Melting/freezing point	Not available.	p) Auto ignition temp.	Not available.
e) Boiling point/range:	Not available.	q) Decomposition temperature	Not available.
g) Flash point:	Not available.	r) Viscosity	Not available.
h) Evaporation rate:	Not available.		
i) Flammability:	Not available.		
j) Explosive properties:	Not available.		
k) Vapour pressure	Not available.		
l) Vapour density	Not available.		
Other information:	Not available.		

10. STABILITY AND REACTIVITY.**10.1 Reactivity**

No data available

10.2 Chemical Stability

Stable under recommended storage conditions (See relevant Label/Instruction for use).

10.3 Possibility of hazardous reactions

No data available.

10.4 Conditions to avoid:

Extreme heat.

10.5 Materials to avoid:

No data available.

10.6 Hazardous decomposition products

Other decomposition products - no data available.

11. TOXICOLOGICAL INFORMATION.**11.1 Information on toxicological effects****Acute toxicity:**

No data available.

Skin corrosion/irritation

No data available.

Serious eye damage/irritation.

No data available.

Respiratory or skin sensitisation.

No data available.

Germ cell mutagenicity.

No data available.

Carcinogenicity.

IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

Reproductive toxicity.

No data available.

Specific target organ toxicity - single exposure.

No data available.

Specific target organ toxicity - repeated exposure.

No data available.

Aspiration hazard.

No data available.

Potential health effects.

Potential biohazard, contains human source material.

Additional information.

RTECS: Not available.

12. ECOLOGICAL INFORMATION**12.1 Toxicity.**

No data available.

12.2 Persistence/Biodegradability.

No data available.

12.3 Bioaccumulation potential.

No data available.

12.4 Mobility in soil.

No data available.

12.5 Other adverse effects.

No data available.

13. DISPOSAL CONSIDERATIONS.**13.1 Waste Treatment methods.****Product.**

Offer surplus and non-recyclable solutions to a licensed disposal company.

Contaminated Packaging.

Dispose of as an unused product.

14. TRANSPORT INFORMATION.

RID/ADR:			
UK Road Class:	-	UK Road Packaging Group:	-
UN No. (Road):	-	RID Class No.	-
Proper Shipping Name:	Not dangerous goods.	RID Pack Group:	-
Hazchem Code:	-	CEPIC TEC-R No.	-
ADR Class No.	-	ADR Class:	-
ADR Pack Group:	-	ADR Label No:	-

IMDG:			
IMDG Class:	-	IMDG Pack Group:	-
UN No. (Sea):	-	MFAG:	-
Proper Shipping Name:	Not dangerous goods.	IMDG Page No:	-
EMS:	-		
Marine pollutant:	-		

IATA:			
Air Class:	-	Air Pack Group:	-
UN Air No.	-		
Proper Shipping Name:	Not dangerous goods.		

14.6 Special precautions for user.

No data available.

15. REGULATORY INFORMATION.

This safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006.

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

No data available.

15.2 Chemical Safety Assessment.

A chemical safety assessment has not been carried out for this product.

16. OTHER INFORMATION**Further Information**

Diagnostic Reagents Ltd plasmas are prepared from human plasma donations each of which have been individually tested and found to be negative for Hbs antigen, HCV and HIV antibodies by approved test methods. We recommend normal precautions should be taken for handling and disposal of potentially infectious material. All the above information is based on current knowledge at the time of publication and follows stipulated regulations. Diagnostic Reagents Ltd is not responsible for any errors or lack of information given in the above literature. The information contained in this SDS does not constitute an assessment of work place risks and is intended only as a guide to the appropriate precautionary handling of a material by a trained person using this product. The customer should undertake a formal COSHH assessment which should ensure that employees are aware of the hazards / precautions detailed in this SDS. The COSHH assessment should ensure that the recommended safety equipment is available and where applicable, that the exposure limits are not being exceeded. Diagnostic Reagents Ltd will not therefore be responsible for damages resulting from use of or reliance upon this information.