MATERIAL SAFETY DATA SHEET

Product Name: Deficiency or Inhibition plasma: alpha2-Antiplasmin, Antithrombin, beta2-Glycoprotein, Factor V, Factor VII, Factor VIII, Factor IX, Factor X, Factor XI, Factor XII, Factor XIII, Heparin Co-Factor II, Plasminogen, Plasminogen.Activator-Inhibitor (PAI), Prekallicrein, Protein C-Inhibitor (PCI), Prothrombin (Factor II), Thrombin-activatable Fibrinolyse-Inhibitor (TAFI), von Willebrand Factor (vWF)

Product Reference: A2AP-LDP, AT-LDP, ATHC-LDP, APOH-LDP, F2-INH1F, F5-INH1F, F7-INH1F, F7-INH2F, F7-INH3F, F8-INH1, F8-INH2, F8-INH3, F8-INH1F, F8-INH2F, F8-INH3F, F9-INH1, F9-INH1F, F10-INH1F, F10-INH2F, F10-INH3F, F11-INH1F, F11-INH2F, F11-INH3F, F12-INH1F, F13-LDP, HC2-LDP, PG-LDP, PAI-LDP, PCI-LDP, F2-INH1, F2-INH2, F2-INH3, TAFI-LDP, VWF-LDP, VWF-T1-DP, VWF-T2A-DP, VWF-T2B-DP, VWF-T3-DP.

MATERIAL SAFETY DATA SHEET

ENGLISH

SECTION 1: PRODUCT & COMPANY IDENTIFICATION

1.1 Product identifier

Please see page 1.

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

For in vitro research use only.

1.3 Details of the manufacturer and supplier of the safety data sheet

CoaChrom Diagnostica GmbH
Hauptstrasse 5
2344 Maria Enzerdorf
Austria
Phone: +43-1-2362221
Fax: +43-1-236222111
E-mail address: info@coachrom.com

1.4 Emergency telephone number

Phone: +43-1-2362221

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]: Not classified.

Adverse physicochemical, human health and environmental effects:
Human plasma was tested and found negative by FDA accepted methods for Anti-HIV 1/2, Anti-HTLV I & II, HBsAg, Anti-HCV, Syphilis, HBC Ab, HIV-1 p24 Ag or HIV-1 RNA, HCV RNA and HBV RNA. Donors are screened for CJD (Creutzfeld-Jakob Disease). Nevertheless, it should be handled by personnel trained in the proper procedures for handling potential viral contaminants

2.2 Label elements

Not applicable.

2.3 Other Hazards

No additional information available.

SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS

3.1 Substances

Not applicable.

3.2 Mixtures

Hazardous ingredients:

Name of the constituents	CAS / EG / REACH	Classification of the substance according to 1272/2008 (CLP)	Concentration
Human Plasma	Not classified	Not classified	>99%

3.3 Other information

Do not inject or ingest.

This product contains material of animal origin and should be considered as potentially capable of transmitting infectious diseases. The preparation contains material of human origin which has been tested and found negative for HBSAg, anti-HIV and HCV. As with all materials of human origin, this product should be regarded as potentially hazardous to health. Therefore, it should be handled in compliance with appropriate laboratory safety procedures to minimize the risk of transmitting infectious pathogens.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures General information

If symptoms develop or when in doubt, seek medical attention (show this safety data sheet). Never give anything by mouth to an unconscious person. Do not leave victim unattended.

After inhalation

IF INHALED: Remove victim to fresh air. Keep warm and at rest. If irritation occurs, seek medical attention.

After skin contact

SKIN CONTACT: Wash off immediately with plenty of soap and water. Take off immediately all contaminated clothing. Wash contaminated clothing before reuse. If skin reaction occurs, seek medical attention.

After eye contact

EYE CONTACT: Rinse immediately with plenty of water for at least 15 minutes holding the eyelids open. If possible. remove contact lenses. Continue to rinse. Seek medical attention preferably an ophthalmologist.

After ingestion

INGESTION: get immediately medical attention. Do not induce vomiting. Never give anything by mouth to an unconscious person.

4.2 Most important symptoms and effects, both acute and delayed

May cause irritation. Potential viral infection.

4.3 Indication of any immediate medical attention and special treatment needed

Notes to physician: In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.

Specific treatments: No specific treatment.

Protection of first-aiders: No action shall be taken involving any personal risk or without suitable training.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media

Product itself is non-combustible; adapt fire-extinguishing measures to surrounding areas.

Unsuitable extinguishing media

Water spray.

5.2 Special hazard arising from the substance or mixture

In the event of fire, the following can be released: Carbon dioxide (CO_2); Carbon monoxide (CO).

5.3 Advice for firefighters

In the event of a fire: Wear protective equipment. Self-contained breathing apparatus.

Do not allow extinguishing water to enter sewerage or any water course. Do not breathe fire/explosion fumes.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal protections, protective equipment and emergency procedures

Refer to protective measures listed in section 7 and 8. Avoid contact with skin, eyes and clothing Avoid dust formation. Do not breathe gas/mist/vapors.

6.2 Environmental precautions

Prevent further spillage if safe. Do not allow product to enter drains or any water course. Avoid release to the environment.

6.3 Methods and material for containment and cleaning up

Do not place spilled material back in the original container. Collect spilled material with absorbent material. Clean contaminated surfaces and devices in compliance with all applicable legal requirements and regulations. Transfer to suitable, closed and labelled containers for storage/disposal.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handing Advice on safe handing

For safe product handling, select and apply appropriate prevention and control measures that will reduce to a minimum the intrinsic risk hazard. Design and operate processes, insofar as the state of technology permits, in such a way that dangerous substances may not be released / contact with the skin can be ruled out.

General protective and hygiene measures

Do not eat, drink or smoke during work time. Keep away from food, drink and animal feeding stuffs. Wash hands and skin before breaks and after work. Do not inhale vapors. Avoid contact whit eyes and skin. Remove soiled or soaked clothing immediately.

Advice on protection against fire and explosion

No special measures necessary.

7.2 Conditions for safe storage, including any incompatibilities Technical measures and storage conditions

Keep container tightly closed in a cool, well-ventilated place.

Incompatible materials

No data available.

Recommended storage temperature

Store according to printed information on vial and certificate of analysis. All frozen items are stored at -60 to -80°C. All lyophilized proteins are stored at 2°C to 8°C. All glycerol containing proteins are stored at -10°C to -20°C. Containers which are opened must be carefully closed and kept upright to prevent leakage.

7.3 Specific end uses

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

SECTION 8: EXPOSURE CONTROLS, PERSONAL PROTECTION

8.1 Control parameters

Occupational exposure limit values

No data available.

Biological limit values

No data available

8.2 Exposure controls

Appropriate engineering controls

Technical measures and appropriate working operations should be given priority over the use of personal protective equipment. Any measure taken shall comply with good hygiene practice.

Personal protective equipment

During product handling, wear appropriate protective clothing in compliance with the applicable rules.

Respiratory protection

Give preference to operation under a dust extractor. Use type N95 (US) or type P1 (EN 143) dust masks. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Hand/skin protection

During handling, wear appropriate protective gloves. Prior to use, check in any case suitability of protective glove for the specific workplace conditions. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

Protective gloves must be tested and approved under EN 374 standard.

Replace protective gloves immediately when they become worn and

damaged.

Eye / face protection

Use equipment for eye and face protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Body protection

The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Other

No data available.

Environmental exposure controls

Prevent further spillage/release of material if safe. Do not allow product to enter drains or any water course. Avoid release to the environment.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Property			
Appearance	Frozen	Lyophilized	Glycerol
Color	Clear to opaque	White/Yellow	Clear to opaque
Odour	ND	ND	ND
pH value	ND	ND	ND
Boiling point	ND	ND	ND
Melting point	ND	ND	ND
Decomposition point	ND	ND	ND
Flash point	ND	ND	ND
Auto-ignition temperature	ND	ND	ND
Oxidising properties	ND	ND	ND
Explosive properties	ND	ND	ND
Flammability	ND	ND	ND
Lower flammability or explosive limits	ND	ND	ND
Upper flammability or explosive limits	ND	ND	ND
Vapour pressure	ND	ND	ND
Vapour pressure	ND	ND	ND
Vapour density	ND	ND	ND
Evaporation rate	ND	ND	ND
Relative density	ND	ND	ND
Solubility	ND	ND	ND
Solubility in water	ND	ND	ND
Partition coefficient: n-octano/water viscosity	ND	ND	ND
Other information	ND	ND	ND

ND: No data available.

9.2 Other information

No data available.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

No dangerous reactions known if handled in compliance with applicable provisions/under normal conditions of use.

10.2 Chemical stability

The preparation is stable if handled and stored as recommended under section 7.

10.3 Possibility of hazardous reactions

None if used for the intended purpose.

10.4 Conditions to avoid

None if used for the intended purpose.

10.5 Incompatible materials

None known.

10.6 Hazardous decomposition products

None if used for the intended purpose.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Effects	
Acute oral toxicity	ND
Acute dermal toxicity	ND
Acute inhalational toxicity	ND
Skin corrosion/irritation	ND
Serious eye damage/eye irritation	ND
Respiratory or skin sensitisation	ND
Germ cell mutagenicity	ND
Reproductive toxicity	ND
Carcinogenicity	ND
Specific target organ toxicity: - - **Single exposure** - **Repeated exposure**	ND
Aspiration hazard	ND

ND: No data available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Toxicity	
Fish toxicity - **Acute** - **Chronic**	ND
Daphnia toxicity - **Acute** - **Chronic**	ND
Algae toxicity - **Acute** - **Chronic**	ND
Bacteria toxicity - **Acute** - **Chronic**	ND

ND: No data available.

12.2 Persistence and degradability

No data available.

12.3 Bio-accumulative potential

No data available.

12.4 Mobility in soil

No data available.

12.5 Results of PBT and vPvB assessment

Assessment	
PBT assessment	ND
vPvB assessment	ND

ND: No data available.

12.6 Other adverse effects

No data available.

12.7 Other information

Do not discharge product unmonitored into the environment.

SECTION 13: WASTE DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product

Dispose of waste in compliance with national rules and consultation with environmental services. The waste code is established in consultation with your regional waste disposer.

13.1 Waste treatment methods Product

Dispose of waste in compliance with national rules and consultation with environmental services. The waste code is established in consultation with your regional waste disposer.

Packaging

Empty properly packaging. Completely emptied packaging or practically empty packaging containing residues shall be disposed of properly in consultation with your regional waste disposer.

SECTION 14: TRANSPORT INFORMATION

The product is not covered by international regulations on the transport of dangerous goods (IMDG, IATA, ADR/RID).

SECTION 15: REGULATORY INFORMATION

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

This MSDS file is comply to the requirements described on the Regulation (EC) No 1907/2006 (REACH) and 1272/2008 (CLP).

15.2 Chemical safety assessment

No data available.

SECTION 16: OTHER INFORMATION

16.1 Key literature references and sources for data

Regulation EC 1907/2006(REACH), Regulation (EC) 1272/2008 (CLP) its current version.

Regulations concerning the International Carriage of Dangerous Goods according to ADR, RID, IMDG, IATA in their current version. The data sources used to determine physical, toxic and ecotoxic data, are indicated directly in the corresponding section of this SDS.

The above information is based on our present-day knowledge and experience. The information provided above is not a technical specification and does not guarantee any properties or performance and does not represent any contractual relationship.

CoaChrom Diagnostica and its appointed agents/distributors or OEM contractors shall not be held liable for any damage resulting from or from contact with the products included in the kit.

16.2 Abbreviations and acronyms

ADR: European Agreement Concerning the International Carriage of Dangerous Goods by Road

CLP: European Regulation on Classification, Labelling and Packaging of Substances and Mixtures

CMR : cancerogen mutagen reprotoxic

IATA-DGR: International Air Transport Association - Dangerous Goods

Regulations IMDG: International Maritime Dangerous Goods code

NIOSH: National Institute for Occupational Safety and Health (NIOSH) in the

U.S. PBT: Persistent, Bioaccumulative, Toxic

ReaCH: European Union Regulation on Registration, Evaluation, Authorisation and restriction of

CHemicals RID: International Rule for Transport of Dangerous Substances by Rail

vPvB: very Persistent, very Bioaccumulative