edited on: 07-Jun-2017

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Coagulation Reference (5 x 1 mL)	REF 5220110
Coagulation Reference (50 x 1 mL)	REF 5220120
Coagulation Reference f. Ceveron® alpha (5 x 1 mL)	REF 5220130
Coagulation Reference f. Ceveron® alpha (5 x 1 mL)	REF 5220135
TECHNOCLOT® Reference (10 x 1 mL)	REF 5220170
TECHNOCLOT® Reference (50 x 1 mL)	REF 5220175
AK-Calibrant (4 x 1 mL)	REF 5010004
AK-Verification Kit (3 x 1 mL)	REF 5010024
Coagulation Control N (5 x 1 mL)	REF 5020040
Coagulation Control N (50 x 1 mL)	REF 5020050
Coagulation Control N f. Ceveron® alpha (5 x 1 mL)	REF 5020020
Coagulation Control N f. Ceveron® alpha (50 x 1 mL)	REF 5020025
TECHNOCLOT® Control N (10 x 1 mL)	REF 5020070
TECHNOCLOT® Control N (50 x 1 mL)	REF 5020075
Coagulation Control A (5 x 1 mL)	REF 5021055
Coagulation Control A (50 x 1 mL)	REF 5021060
TECHNOCLOT® Control A2 (5 x 1 mL)	REF 5021062
TECHNOCLOT® Control A2 (50 x 1 mL)	REF 5021064
Coagulation Control A f. Ceveron® alpha (5 x 1 mL)	REF 5021035
Coagulation Control A f. Ceveron® alpha (50 x 1 mL)	REF 5021040
TECHNOCLOT® Control A (10 x 1 mL)	REF 5021070
TECHNOCLOT® Control A (50 x 1 mL)	REF 5021075
Coagulation Control AK (5 x 1 mL)	REF 5011050
Coagulation Control AK (50 x 1 mL)	REF 5011060
Coagulation Control AK f. Ceveron® alpha (5 x 1 mL)	REF 5011030
Coagulation Control AK f. Ceveron® alpha (5 x 1 mL)	REF 5011035
Platelet Poor Plasma (5 x 2 mL)	REF 5343022

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

Identified use: For in vitro diagnostic use

1.3. Details of the supplier of the safety data sheet

Technoclone Herstellung von Diagnostika
und Arzneimitteln Gesellschaft mbH
Brunner Str. 67
1230 Wien
Österreich
Tel. +43 1 86373-0
Fax +43 1 86373-44

Email (competent person): products@technoclone.com

1.4 Emergency telephone number: +43 1 86373-10 (8:00 – 16:00)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

No hazardous products according to 1907/2006/EC and 1272/2008/EC

2.2. Label elements

not applicable

2.3. Other hazards

The products contain human plasma that tested non-reactive for HIV antibody, Hepatitis B Surface Antigen and Anti-HCV. These products, as with all human based specimens, should be regarded as potentially infectious and handled with proper laboratory safety procedures for handling of biological material.

SECTION 3: Composition/Information on ingredients

3.2. Mixtures

There are no components to declare according to the applicable regulations.

SECTION 4: First aid measures

4.1. Description of first aid measures

General

Remove contaminated clothes

Contact with eyes

Wash immediately with plenty of water or normal saline for at least 15 minutes. Keep eye lid open with the finger.

Contact with skin

Wash immediately affected area with soap or mild detergent and plenty of water until removal of the mixture (15 to 20 minutes).

Ingestion

If swallowed rinse mouth with plenty of water provided person is conscious. Do not induce vomiting. Get medical advice if adverse symptoms appear.

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

Toxic symptoms and effects are not known.

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

Monitoring or antidotes not known.

SECTION 5: Firefighting measures

5.1. Extinguishing media

suitable extinguishing media: water spray or regular foam, CO_2, dry powder

unsuitable extinguishing media: not known

5.2 Special hazards arising from the substance or mixture

No data available

5.3. Advice for fire fighters

Protective actions:
Water jets can be used successfully to cool containers exposed to the fire and disperse fumes.

Equipment for self-protection:
Breathing apparatus (SCBA), flame and chemical resistant clothing (boots, gloves, overalls, eye and face protection). Equipment must be conformed to the national/international standards and used in highest condition of protection on the basis of the information reported in the previous sub-sections.

SECTION 6: Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Wear gloves and avoid contact with the substance or mixture

6.2. Environmental precautions

No special precautions required.

6.3. Methods and material for containment and cleaning up

Collect spilled material dry and clean with plenty of water

Discard spilled material according to standard regulations.

6.4. Reference to other sections

Use personal protection equipment as described in Section 8 and dispose waste according to instructions given in Section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Handle in a well ventilated place, and away from sparkles and flames. Keep the mixture away from drains, surface or ground waters. Wear suitable Personal Protection Equipment (see section 8). Do not eat, drink and smoke in the working areas. Wash hands with soap and water after handling the mixture. Remove contaminated clothing and protective equipment before entering eating areas.

7.2 Conditions for safe storage, including any incompatibilities

Recommended temperature: store at 2 to 8°C
Avoid light exposure and keep away from heat sources. Work in a well ventilated workplace. Keep containers tightly closed and labelled with the name of the product. Avoid environmental release. Keep away from food and drinks.

7.3. Specific end use(s)

The product is intended vor in-vitro diagnostic use. Read and understand safety notes as given in the package insert. Use the product in accordance with the Good Laboratory Practice (GLP)

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Workplace exposure limit values are not established.

8.2. Exposure Control

8.2.1. Appropriate engineering controls

Appropriate risk management measures, that must be adopted at the workplace, have to be selected and applied, following the risks assessment carried out by the employer, in connection with his working activity. If the results of this evaluation show that the general and collective prevention measures are not sufficient to reduce the risk, and if you cannot prevent exposure to the mixture by other measures, adequate personal protective equipments must be adopted, complying with relevant technical national/international standards.

8.2.2. Individual protection measures, such as Personal Protective Equipment (PPE)

a) General protective and hygienic measures:
The usual precautionary measures are to be adhered to when handling chemicals or biological material.

b) Eye/face protection: Use of safety glasses is recommended.

c) Skin protection:
i) protection of hands
The glove material has to be impermeable and resistant to the product/the substance/the mixture. Due to missing tests no recommendation on the glove material can be given for the product/the substance/the mixture. Choose glove material with respect to penetration time, permeation rates and degradation. The selection of the suitable gloves does not only depend on the material, but also on further quality features and varies between manufacturers. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application. Information about the exact penetration time should be received from the manufacturer of the protective gloves and has to be observed.
ii) other protective measures: not required

d) Respiratory protection: Respiratory protection not required.

e) Thermal hazards: No information available.

f) Environmental exposure controls: Avoid release into the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance:	white to yellowish powder
Odor:	odourless
pH:	pH 6-8
Density:	1
Solubility:	readily soluble in water

9.2. Other information

No further information available.

SECTION 10: Stability and Reactivity

10.1. Reactivity

The product is considered not reactive under normal conditions of usage.

10.2. Chemical Stability

The product is stable until the expiry date shown on the package or the label when stored at the temperature indicated.

10.3. Possibility of hazardous reactions

No hazardous reactions foreseen under normal conditions of storage and use.

10.4. Conditions to avoid

Keep out from heat, water, humidity or light.

10.5. Incompatible materials

Oxidizing agents, strong acid agents and strong alkaline agents.

10.6. Hazardous decomposition products

Thermal decomposition or combustion may include toxic and hazardous fumes of (COx, NOx).

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity:	No data available.
Skin corrosion/irritation:	Prolonged and repeated contact may cause skin irritations.
Serious eye damage/irritation:	May cause eye irritation
Skin and respiratory sensitization:	May cause respiratory irritation
Germ cell mutagenicity:	No data available.
Carcinogenesis:	No data available.
Reproductive toxicity:	No data available.
Specific target organ toxicity (STOT)-single exposure:	No data available.
Specific target organ toxicity (STOT)-repeated exposure:	No data available.
Aspiration hazards:	No data available.

Reasons for the lack of classification:

Where the mixture resulted in a non-classification, this may be due to the availability of data which does not impose a classification for that specific end-point, or due to lack of data or due to availability of inconclusive data or data which are not sufficient to get a classification as for the criteria adopted in regulations mentioned in this data sheet.

SECTION 12: Ecological information

12.1. Toxicity	No data available
12.2. Persistency and degradability	No data available.
12.3. Bioaccumulation potential	No data available
12.4. Mobility in soil	No data available
12.5. Results of PBT and vPvB assessment	not applicable
12.6. Other toxic effects	No data available

SECTION 13: Disposal considerations

National laws on disposal must be considered, local and EU requirements for waste recycling must be respected.

13.1 Waste treatment methods

Used waste product, surplus product or spillage products shall be disposed of in accordance with national state and local laws.

SECTION 14: Transport information

The product is **not** subject to transport regulations according to ADR/RID, IMDG, IATA and DOT.

SECTION 15: Regulatory Information

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

The contained information in this MSDS is in accordance with Annex II of regulation no. 1907/2006 (REACH) and in accordance with ANSI "Standard for Hazardous Industrial Chemicals – Material Safety Sheets – Preparation" (ANSI Z400.1-2004) as recommended by US OSHA.

The product/components are not subject to regulation 93/21/EEC about transport and labeling dangerous substances.

15.2. Chemical safety assessment

Chemical safety assessment for this product/mixture is not necessary according to EC 1907/2006 article 14 paragraph 2.

SECTION 16: Other information

Revisions:
General revision according to regulation (EC) 2015/830)

Abbreviations and Acronyms:

SDS:	Safety Data Sheet
PBT:	Persistence, Bioaccumulation, Toxicity
vPvB:	Very persistent and very bioaccumulative
STOT	specific target organ toxicity
SCBA:	Self-contained breathing apparatus
ADR:	Agreement concerning the carriage of dangerous goods by road
RID	Regulation concerning the international carriage of dangerous goods by rail
IMDG	International Maritime Dangerous Goods code
IATA	International air transport organization
DOT	US Department of Transportation
ANSI	American National Standards Institute
OSHA	Occupational Safety & Health Administration (US)
HBsAG	*Hepatitis Virus B surface antigen*
HCV	*Hepatitis C Virus*
HIV	*Human Immunodeficiency Virus*

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.