

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

1.1. Product identifier

TECHNOTHROMBIN® TGA Kit, 3 x 16 T.	REF 5006010
TECHNOTHROMBIN® TGA RA, 5 x 0.5 mL	REF 5006205
TECHNOTHROMBIN® TGA RA, 50 x 0.5 mL	REF 5006206
TECHNOTHROMBIN® TGA RB, 5 x 0.5 mL	REF 5006209
TECHNOTHROMBIN® TGA RB, 50 x 0.5 mL	REF 5006210
TECHNOTHROMBIN® TGA RC low, 5 x 0.5 mL	REF 5006212
TECHNOTHROMBIN® TGA RC low, 50 x 0.5 mL	REF 5006213
TECHNOTHROMBIN® TGA RC high, 5 x 0.5 mL	REF 5006214
TECHNOTHROMBIN® TGA RC high, 50 x 0.5 mL	REF 5006216
TECHNOTHROMBIN® TGA RD, 5 x 1.5 mL	REF 5006220
TECHNOTHROMBIN® TGA RD, 50 x 1.5 mL	REF 5006222
TECHNOTHROMBIN® TGA SUB, 5 x 1.5 mL	REF 5006235
TECHNOTHROMBIN® TGA SUB, 50 x 1.5 mL	REF 5006230
TECHNOTHROMBIN® TGA Kalibrator Set, 1 Set	REF 5006345
TECHNOTHROMBIN® TGA Control High, 5 x 1 mL	REF 5006320
TECHNOTHROMBIN® TGA Control Low, 5 x 1 mL	REF 5006330

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

Identified use: For research use only

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 product according to 1907/2006/EC and 1272/2008/EC

2.2. Label elements

not applicable

2.3. Other hazards

All chemicals are potentially dangerous. They are therefore only to be handled by specially trained personnel with the necessary care.

Some of the above listed products contain human plasma:

REF 5006010, **REF** 5006320, **REF** 5006330

Human plasma used for these products 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.

Some of the above listed products contain animal by-products from bovine plasma:

REF 5006010, **REF** 5006345

The source animals for these products are undergoing veterinary health inspection and do not show signs of any disease communicable through that product to humans or animals. Nevertheless, these products should be handled with proper laboratory safety procedures.

These mixtures do not contain any components in concentrations of 0.1 % or above, which are classified either as PBT or vPvB.

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, CO₂, dry powder

unsuitable extinguishing media: not known

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5.2 Special hazards arising from the substance or mixture

Thermal decomposition or combustion may generate toxic and hazardous fumes of CO_x, NO_x, Na₂O, SO_x.

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

Do not let the product enter drainage system.

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 for research use. Read and understand safety notes as given in the package insert. Use the product in accordance with the Good Laboratory Practice (GLP)

The product contains bovine material. Bovine serum albumin (BSA) might cause allergic skin reaction and/or allergy or asthma symptoms or breathing difficulties if inhaled.

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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 equipment 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 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.



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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 (CO_x, NO_x, Na₂O, SO_x).

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



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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 products are **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

 <p>The logo for Technoclone TC features the word "technoclone" in a lowercase, italicized sans-serif font above the letters "TC" in a large, bold, black sans-serif font. The "TC" is partially overlaid by five horizontal blue lines.</p>	<p style="text-align: center;">Safety Data Sheet</p> <p style="text-align: center;">according to regulation (EC) 1907/2006, amended by regulation (EU) 2015/830</p>	<p>SDS No. 111</p> <p>version: 09 replaces version 08 from 19-MAY-2010</p>
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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.