



## Safety Data Sheet

according to regulation (EC) 1907/2006, amended  
by regulation (EU) 2015/830

**SDS No. 328**

version: 04  
replaces version 03  
from 06-Mar-2012

*edited on: 18-May-2017*

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

#### 1.1. Product identifier

TECHNOCLOT® PT PLUS (5 x 4 mL) REF 5003220

TECHNOCLOT® PT PLUS (10 x 10 mL) REF 5003222

#### 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

The component "Technoclot PT Plus Solvent" is classified as **skin sensitizing, category 1**, due to its content of Nickelsulfate.

#### 2.2. Label elements

Hazard Pictogram:	GHS07  Nickelsulfate
Signal Word:	Warning
Hazard Statement:	H317 – May cause an allergic skin reaction
Precautionary Statements:	P261, P280, P302+P352, P333 +P313

#### 2.3. Other hazards

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

Products contain animal by-products derived from rabbit brain. 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

Description of the mixtures

Each of the above products contains 2 components of the same volume to each other. The products differ only in the volume contained in the corresponding vials.

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Both components contain a mixture of non-hazardous components and the substances listed below:

Kit componen	Name of substance	Identifier	Concentration (% by weight)	Classification acc. to 1272/2008 EC regulation	Hazard Pictogram	Concentration Limit
Technoclot® PT Plus Reagent	Rabbit brain powder	Not applicable	< 1%	None	None	none
Technoclot® PT Plus Solvent	Nickelsulfate-Hexahydrate	EG No. 232-104-9 CAS No. 10101-97-0	0,01% < C < 0,1 %	Skin sensitizing, cat.1, H317*		0,01%
	Polybrene	CAS No. 28728-55-4	< 0,1 %	Acute Toxicity, Oral; cat. 1; H302*		1%
	ProClin300	CAS No 55965-84-9 Index No. 613-167-00-5	< 0,04 % (corresponds to < 0,0015 % MIT)	Skin sensitizing, cat.1	None	0,0015 %

\* for complete text of hazard statements see Section 16

## 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<sub>2</sub>, dry powder

unsuitable extinguishing media: not known

### 5.2. Special hazards arising from the substance or mixture

Thermal decomposition or combustion may generate toxic and hazardous fumes of CO<sub>x</sub>, NO<sub>x</sub>, Na<sub>2</sub>O, SO<sub>x</sub>.



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### 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.

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## SECTION 6: Accidental Release Measures

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### 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 with inert absorbent material 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.

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## SECTION 7: Handling and storage

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### 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 in-vitro diagnostic use (*ODER 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)

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## SECTION 8: Exposure controls/personal protection

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### 8.1. Control parameters

Workplace exposure limit values are not established.

### 8.2. Exposure Control



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### 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.

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## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

Appearance: white to grey powder and colourless liquid respectively

Odor: odourless

pH: pH 6-8

Density: 1

Solubility: lyophilized product readily soluble in water, liquid reagent readily miscible with water

### 9.2. Other information

No further information available.

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## 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.



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### 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<sub>x</sub>, NO<sub>x</sub>, Na<sub>2</sub>O, SO<sub>x</sub>.

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## SECTION 11: Toxicological information

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### 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.

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## SECTION 12: Ecological information

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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

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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.

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## SECTION 14: Transport information

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



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### 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)

#### Information related to the Regulation EC/1272/2008

#### List of relevant Hazard and Precaution Statements

H302	Harmful if swallowed
H317	May cause an allergic skin reaction
P261	Avoid breathing dust and aerosols
P280	Wear protective gloves and eye protection
P302+P352	If on skin: wash with plenty of water
P333 +P313	If skin irritation or rash occurs: Get medical advice

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.