

Safety Data Sheet

Technoclot PT Plus



SDS No. 6C00.01
p 1/7 EN R01

Temp.: TF0604.01
Att: 05 to D00068

ACCORDING TO EC-REGULATIONS 1907/2006 (REACH), 1272/2008 (CLP) & 2020/878

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Product Name/Reference No.	Technoclot PT Plus	5 x 4 mL	REF 5003220
	Technoclot PT Plus	10 x 10 mL	REF 5003222
Product Components	Component 1	Technoclot PT Plus Reagent	5 x 4 mL and 10 x 10 mL, resp.
	Component 2	Technoclot PT Plus Solvent	5 x 4 mL and 10 x 10 mL resp.

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

Identified Use(s)	For professional users only
Uses Advised Against	Not known.

1.3 Details of the supplier of the safety data sheet

Manufacturer

Company Identification	Technoclone Herstellung von Diagnostika und Arzneimitteln GmbH
Address of Manufacturer	Brunner Strasse 67 1230 Vienna Austria
Postal code	1230
Telephone:	+43 1 86373-0
Fax	+43 1 86373-44
E-mail	products@technoclone.com
Office hours	8:00 – 16:00

1.4 Emergency telephone number

Emergency Phone No.	+43 1 86373-0
Contact	products@technoclone.com
National response center	
Address	NHS Direct
Emergency Phone No.	+44 111

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Component 1	Technoclot PT Plus Reagent	Regulation (EC) No. 1272/2008 (CLP) Not classified as dangerous for supply/use
Component 2	Technoclot PT Plus Solvent	Not classified as dangerous for supply/use

2.2 Label elements

Product Name	Technoclot PT Plus
Hazard Pictogram(s)	None.

2.3 Other hazards

Component 2 (Technoclot PT Plus Solvent) contains Nickel Sulphate. May cause allergic reactions.

2.4 Additional Information

Component 1	Technoclot PT Plus Reagent	Contains animal derived material – potentially biohazardous
Component 2	Technoclot PT Plus Solvent	The usual precautions for handling chemicals should be observed.

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SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Not applicable.

3.2 Mixtures

Component		HAZARDOUS INGREDIENT(S)	CAS No.	EC No. / REACH Registrati on No.	%W/W	Hazard Statement(s)	Hazard Pictogram(s)
Component 1	Technoclot PT Plus Reagent	none	n.a.	n.a.	n.a.	n.a.	n.a.
Component 2	Technoclot PT Plus Solvent	Sulfuric acid, nickel(2+) salt, hydrate (1:1:6)	10101-97-0	600-152-3	< 0.1	Acute Tox. 4 H302 Skin Irrit. 2 H315 Skin Sens. 1 H317 Acute Tox. 4 H332 Resp. Sens. 1 H334 Muta. 2 H341 Carc. 1A H350i Repr. 1B H360D STOT RE 1 H372 Aquatic Acute 1 H400 Aquatic Chronic 1 H410	GHS07 GHS08 GHS09
		Hexadimethrine bromide	28728-55-4	684-236-5	< 0.001	Acute Tox. 4 H302	GHS07
		ProClin300	55965-84-9	611-341-5	< 0.00015	Acute Tox. 3 H301 Acute Tox. 2 H310 Skin Corr. 1C H314 Skin Sens. 1A H317 Eye Dam. 1 H318 Acute Tox. 2 H330 Aquatic Acute 1 H400 Aquatic Chronic 1 H410	GHS06 GHS05 GHS07 GHS09

HAZARDOUS INGREDIENT(S)	CAS No.	Specific concentration limit		M-factor	ATE
Sulfuric acid, nickel(2+) salt, hydrate (1:1:6)	10101-97-0	Skin Irrit. 2	C>= 20.00 <= 100.00		Acute Tox. 4 (H302) : 500 Acute Tox. 4 (H332) : 11
		Skin Sens. 1	C>= 0.01 <= 100.00		
		STOT RE 1	C>= 1.00 <= 100.00		
		STOT RE 2	C>= 0.10 < 1.00		
reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)	55965-84-9	Skin Corr. 1C	C>= 0.60 <= 100.00	Aquatic Acute 1: 100 Aquatic Chronic 1: 100	Acute Tox. 3 (H301) : 100 Acute Tox. 2 (H310) : 50 Acute Tox. 2 (H330) : 0.5
		Skin Irrit. 2	C>= 0.06 < 0.60		
		Skin Sens. 1A	C>= 0.0015 <= 100.00		
		Eye Dam. 1	C>= 0.60 <= 100.00		
Eye Irrit. 2	C>= 0.06 < 0.60				

Contains no non-classified vPvB substances or substances with a Union workplace exposure limit.
For full text of H/P Statements see section 16.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

Inhalation	If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.
Skin Contact	Wash skin with water.
Eye Contact	Flush eyes with water for at least 15 minutes.
Ingestion	Wash out mouth with water.

4.2 Most important symptoms and effects, both acute and delayed

None anticipated. Treat symptomatically.

4.3 Indication of any immediate medical attention and special treatment needed

Unlikely to be required but if necessary treat symptomatically.

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SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable Extinguishing media As appropriate for surrounding fire.
Unsuitable extinguishing media None.

5.2 Special hazards arising from the substance or mixture

None anticipated. Heating may cause decomposition.

5.3 Advice for firefighters

As appropriate for surrounding fire.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Provide adequate ventilation. Wear suitable gloves if prolonged skin contact is likely.

6.2 Environmental precautions

Do not release large quantities into the surface water or into drains.

6.3 Methods and material for containment and cleaning up

Sweep spilled substances into containers if appropriate moisten first to prevent dusting.

6.4 Reference to other sections

See Also Section 8, 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Not known.

7.2 Conditions for safe storage, including any incompatibilities

Storage temperature 2°C to 8°C
Storage life Stable under normal conditions.
Incompatible materials None known.

7.3 Specific end use(s)

In vitro diagnostic use

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

8.1.1 Occupational Exposure Limits No Occupational Exposure Limit assigned.

8.2 Exposure controls

8.2.1. Appropriate engineering controls Ensure adequate ventilation.

8.2.2. Personal protection equipment

Eye Protection Wear eye protection with side protection (EN166).
Skin protection Gloves recommended
Respiratory protection Normally no personal respiratory protection is necessary.
Thermal hazards None known.

8.2.3. Environmental Exposure Controls Do not release large quantities into the surface water or into drains.

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SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Physical state			
Component 1	Technoclot PT Plus Reagent	solid (lyoph.)	
Component 2	Technoclot PT Plus Solvent	liquid	
Colour			
Component 1	Technoclot PT Plus Reagent	white-yellowish	
Component 2	Technoclot PT Plus Solvent	without colour	
Odour – all components			odourless
Melting point/freezing point			Not known.
Boiling point or initial boiling point and boiling range			Not applicable.
Flammability			Not known.
Lower and upper explosion limit			Not known.
Flash Point			Not applicable.
Auto-ignition temperature			Not known.
Decomposition Temperature			Not known.
pH			Not known.
Kinematic Viscosity			Not known.
Solubility			Solubility (Water) : readily miscible. Solubility (Other) : Not known
Partition coefficient n-octanol/water (log value)			Not known.
Vapour pressure			Not known.
Density and/or relative density			Not known.
Relative vapour density			Not known.
Particle characteristics			Not known.

9.2 Other information

None.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

None anticipated.

10.2 Chemical Stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

No hazardous reactions known if used for its intended purpose.

10.4 Conditions to avoid

None anticipated.

10.5 Incompatible materials

Not known.

10.6 Hazardous decomposition products

No hazardous decomposition products known.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity - Ingestion	Low acute toxicity
Acute toxicity - Skin Contact	Low acute toxicity
Acute toxicity - Inhalation	Low acute toxicity

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Skin corrosion/irritation	Non-irritant
Serious eye damage/irritation	Non-irritant
Skin sensitization data	Not classified
Respiratory sensitization data	Not classified
Germ cell mutagenicity	There is no evidence of mutagenic potential.
Carcinogenicity	No evidence of carcinogenicity.
Reproductive toxicity	Not classified
Lactation	Not classified
STOT - single exposure	Not classified
STOT - repeated exposure	Not classified
Aspiration hazard	Not classified

11.2 Information on other hazards

Not known.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Toxicity - Aquatic invertebrates	Low toxicity to invertebrates.
Toxicity - Fish	Low toxicity to fish.
Toxicity - Algae	Low toxicity to algae.
Toxicity - Sediment Compartment	Not classified.
Toxicity - Terrestrial Compartment	Not classified.

12.2 Persistence and degradability

Not known.

12.3 Bioaccumulative potential

Not known.

12.4 Mobility in soil

Not known.

12.5 Results of PBT and vPvB assessment

Not known.

12.6 Endocrine disrupting properties

None known.

12.7 Other adverse effects

Not known.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Dispose at suitable refuse site.

13.2 Additional Information

No special precautions are required for this product.

SECTION 14: TRANSPORT INFORMATION

Not classified as hazardous for transport.

14.1 UN number or ID number

Not applicable

14.2 UN proper shipping name

Not applicable

14.3 Transport hazard class(es)

Not applicable

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14.4 Packing group

Not applicable

14.5 Environmental hazards

Not classified as a Marine Pollutant.

14.6 Special precautions for user

Not known

14.7 Maritime transport in bulk according to IMO instruments

Not known

SECTION 15: REGULATORY INFORMATION

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

European Regulations - Authorisations and/or Restrictions on Use

Candidate List of Substances of Very High Concern for Authorisation Not listed

REACH: ANNEX XIV list of substances subject to authorisation Not listed

REACH: Annex XVII Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles Nickel (II)sulphate hexahydrate (10101-97-0), reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (55965-84-9)

Community Rolling Action Plan (CoRAP) Not listed
Regulation (EC) N° 2019/1021 of the European Parliament and of the Council on persistent organic pollutants Not listed
Regulation (EC) N° 1005/2009 on substances that deplete the ozone layer Not listed
Regulation (EU) N° 649/2012 of the European Parliament and of the Council concerning the export and import of hazardous chemicals Not listed

National regulations

Other Not known.

Other Not known.

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Other Not known.

Other Not known.

15.2 Chemical Safety Assessment

A REACH chemical safety assessment has not been carried out.

SECTION 16: OTHER INFORMATION

Major additions, deletions or changes to previous version are indicated by lines in the margin.

LEGEND

Hazard Pictogram(s)

GHS05: Corrosion

GHS06: Acute Toxicity

GHS07: Harmful

GHS08: Serious Health Hazard

GHS09: Environmental Hazard

Hazard classification (s)

Acute Tox. 3 : Acute toxicity, Category 3

Acute Tox. 4 : Acute toxicity, Category 4

Acute Tox. 2 : Acute toxicity, Category 2

Skin Corr. 1C : Skin corrosion/irritation, Category 1C

Skin Corr. 2 : Skin corrosion/irritation, Category 2

Skin Sens. 1 : Skin sensitization, Category 1

Skin Sens. 1A : Skin sensitization, Category 1A

Eye Dam. 1 : Serious eye damage/irritation, Category 1

Resp. Sens. 1 : Respiratory sensitization, Category 1

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Hazard Statement(s) Muta. 2 : Germ cell mutagenicity, Category 2
Carc. 1A : Carcinogenicity, Category 1A
Repr. 1B : Reproductive toxicity, Category 1B
STOT RE 1 : Specific Organ Toxicity — repeated exposure, Category 1
Aquatic Acute 1 : Hazardous to the aquatic environment, Acute, Category 1
Aquatic Chronic 1 : Hazardous to the aquatic environment, Chronic, Category 1
H301: Toxic if swallowed.
H302: Harmful if swallowed.
H310: Fatal in contact with skin.
H314: Causes severe skin burns and eye damage.
H315: Causes skin irritation.
H317: May cause an allergic skin reaction.
H318: Causes serious eye damage.
H330: Fatal if inhaled
H332: Harmful if inhaled.
H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled
H341: Suspected of causing genetic defects.
H350i: May cause cancer by inhalation.
H360D: May damage the unborn child.
H372: Causes damage to organs through prolonged or repeated exposure.
H400: Very toxic to aquatic life.
H410: Very toxic to aquatic life with long lasting effects.

Precautionary Statement(s) None

Acronyms ATE : Acute Toxicity Estimate
CAS : Chemical Abstracts Service
CLP : Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
DNEL : Derived No Effect Level
EC : European Community
EINECS : European Inventory of Existing Commercial Chemical Substances
LTEL : Long term exposure limit
PBT : Persistent, Bioaccumulative and Toxic
PNEC : Predicted No Effect Concentration
REACH : Registration, Evaluation, Authorisation and Restriction of Chemicals
STEL : Short term exposure limit
STOT : Specific Target Organ Toxicity
vPvB : very Persistent and very Bioaccumulative

Key literature references and sources for data used to compile the SDS Regulation (EC) No. 1272/2008 (CLP)

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