

Safety Data Sheet

TECO

In accordance with 1907/2006/EG annex II, 1272/2008 and 2020/878

(All references to EU Regulations and directives are abbreviated into only the numeric term)

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

1.1. Product identifier

Trade name	TEClot PT-S
Article number	A0230-040, A0230-100

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

Identified uses	Perform the one stage Prothrombin Time (PT) test as a fundamental, quantitative screening test for acquired or inherited bleeding disorders and for the determination of the activity of coagulation factors II, V, VII and X in human plasma.
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Uses Advised Against	Use in accordance with the supplier's recommendations.
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1.3. Details of the supplier of the safety data sheet

Company	TECO Medical Instruments Production + Trading GmbH Dieselstr. 1, 84088 Neufahrn i.NB, Germany
Telephone	+49 8773 707 80-0
E-mail	info@teco-gmbh.com

1.4. Emergency telephone number

Poisoning emergency number Munich: 089 19240 or 112.

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

The mixture has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.

Classification according to Directive 67/548/EEC or 999/45/EC as amended.

The full text for all R-phrases is displayed in section 16.

Classification according to Regulation (EC) No 1272/2008 as amended.

This mixture does not meet the criteria for classification according to Regulation (EC) 1272/2008 as amended.

Hazard summary

Physical Hazards	Not classified for physical hazards.
Health Hazards	
Potential Health Effects	
Prolonged inhalation	may result in dizziness and general weakness.
Skin	Prolonged and/or repeated contact may cause irritation and/or dermatitis.
Eyes	May cause eye irritation.
Ingestion	Harmful if swallowed. May cause irritation of the digestive tract.
Environmental Hazards	Hazardous to aquatic life.
Specific Hazards	Avoid contact with eyes and skin. Do not ingest or inhale. Contact with acids may liberate toxic gas.
Main Symptoms	Ingestion may cause irritation and malaise.

2.2. Label elements

Label according to Regulation (EC) No. 1272/2008 as amended

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Hazard pictogram



Signal word

Warning

Hazard statement

H305	May be harmful if swallowed and enters airways
H316	Causes mild skin irritation
H317	May cause an allergic skin reaction
H320	Causes eye irritation
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled

Precautionary statements

P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
P264	Wash hands thoroughly after handling.
P285	In case of inadequate ventilation wear respiratory protection.
P301 + P310	IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician
P304 + P341	IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing
P331	Do NOT induce vomiting
P332 + P313	If skin irritation occurs: Get medical advice/attention
P337 + P313	If eye irritation persists: Get medical advice/attention
P342 + P311	If experiencing respiratory symptom: Call a POISON CENTER or doctor/physician

SECTION 3: Composition/information on ingredients

General Information

Chemical Name	Percent	CAS No./EC.No.	Reach Registration No.
Sodium Propionate	<3.0%	137-40-6 205-290-4	NA
Sodium Azide	<0.1%	26628-22-8 247-852-1	NA
Classification: DSD: T+; R28,R32,R50/53 CLP: Acute Tox. 2; H300, Acute Tox. 1; H310, Aquatic Acute; H400, Aquatic Chronic 1; H410			
Polyethylene glycol tert-octylphenyl ether (Triton X-100)	<0.01%	9306-19-5	NA

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List of Abbreviations	DSD: Directive 67/548/EEC CLP: regulation No. 1272/2008
Composition Comments:	All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume. The full text for all R- and H-phrases is displayed in section 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation	Move to fresh air immediately. If not breathing give artificial respiration. If breathing is difficult, give oxygen. Seek medical attention immediately.
Skin contact	Flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. If irritation develops or persists, seek medical attention.
Eye contact	Immediately flush eyes with plenty of water for at least 15 minutes, occasionally lifting the upper and lower eyelids. Seek medical attention immediately.
Ingestion	If victim is conscious and alert, give 2-4 cups of milk or water. Never give anything by mouth to an unconscious person. Seek medical attention immediately or contact a poison control center.

SECTION 5: Firefighting measures

General Fire Hazard

The product is not flammable

5.1. Extinguishing media

Suitable Extinguishing Media	Extinguish with water spray, carbon dioxide, dry chemical or material appropriate for the surrounding fire.
Unsuitable Extinguishing Media	None known

5.2. Special Hazards Arising From the Substance/Mixture

Sodium azide may form explosive compounds in metal drain lines. When disposing of solutions through plumbing fixture, flush with copious amount of water

5.3. Advise for Firefighters

Special Protective Equipment For Firefighters

Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Special Firefighting procedures

Use standard firefighting procedures and consider the hazards of other involved materials.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For Non-Emergency Personnel	Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing.
For Emergency Responders	Use personal protection as recommended in section 8 of the SDS.

6.2. Environmental Precautions

Do not allow to enter drains, sewers or watercourses. This mixture contains a small amount of sodium azide which can react with copper, lead, brass or solder in plumbing systems and form potentially explosive metal azides. Follow proper disposal procedures.

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6.3. Methods and Material for Containment and Cleaning Up

Absorb spill with vermiculite or other inert material. Dispose of waste in accordance with all applicable federal, state, local and provincial environmental regulations, per Section 13.

6.4. Reference to Other Sections

For personal protection, see section 8 of the SDS. For waste disposal, see Section 13 of the SDS.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Avoid contact with skin and eyes. Wash thoroughly after handling. In case of insufficient ventilation, wear suitable respiratory equipment. Handle and open container with care.

7.2. Conditions for safe storage, including any incompatibilities

Store at 2°-8°C. Store in a closed container away from incompatible materials

SECTION 8: Exposure controls/personal protection

8.1. Control Parameters

Occupational Exposure Limits

UK. EH40 Workplace Exposure Limits (WELs)

Component	CAS No.	Type	Value
Sodium Azide	26628-22-8	STEL	0.3 mg/m ³
		TWA	0.1 mg/mg ³
Sodium Propionate	137-40-6	NA	NA
Polyethylene glycol tert-octylphenyl ether (Triton X-100)	9306-19-5	NA	NA

EU. Indicative Exposure Limit Values, in Directives 91/322/EEC, 2000/39/EC, 2006/15/EC, 2009/161/EU

Component	CAS No.	Type	Value
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		TWA	0.1 mg/mg ³
Sodium Propionate	137-40-6	NA	NA
Polyethylene glycol tert-octylphenyl ether (Triton X-100)	9306-19-5	NA	NA

Biological Limit Values No biological exposure limits noted for the ingredient(s).

Recommended Monitoring Procedures Follow standard monitoring procedures.

Derived No-Effect Level (DNEL) Not available.

Predicted No Effect Concentrations (PNECs) Not available.

Exposure Guidelines

UK EH40 WEL: Skin Designation

Sodium Azide (CAS 26628-22-8) Can be absorbed through the skin.

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8.2. Exposure Controls

Engineering Controls

Provide adequate ventilation. Observe Occupational Exposure Limits and minimize the risk of inhalation of vapors. Provide easy access to water supply and eye wash facilities.

General Information

Personal protective equipment should be chosen according to the CEN standards and in discussion with the supplier of the personal protective equipment.

Eye/Face Protection

Wear approved safety glasses or goggles.

Skin Protection

Hand Protection

Wear appropriate chemical resistant gloves.

Other

Wear lab coat or other protective garments. Remove contaminated clothing promptly.

Respiratory Protection

Under normal conditions, respirator is not required.

Thermal Hazards

None required.

Hygiene Measures

Handle in accordance with good industrial hygiene and safety practices.

Environmental Exposure Controls

Notify managerial or supervisory personnel of all environmental releases.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance

Physical state

solid

Colour

White

Odour

Odorless

Odour threshold

Not Available.

pH

Not Available.

Melting Point/Freezing Point

Not Available.

Initial Boiling Point

Not Available.

Flash Point

Not Available.

Evaporation Rate

Not Available.

Flammability (Solid,gas)

Not Available.

Vapour Pressure

Not Available.

Vapour Density

Not Available.

Relative Density

Not Available.

Solubility(ies)

Soluble in water

Auto-Ignition Temperature

Not Available.

Decomposition Temperature

Not Available.

Viscosity

Not Available.

Explosive Properties

Not Available.

Oxidizing Properties

Not Available.

SECTION 10: Stability and reactivity

10.1. Reactivity

This mixture contains a small amount of sodium azide, which can react with copper, lead brass or solder in plumbing systems and form potentially explosive metal azides.

10.2. Chemical Stability

Material is stable under normal conditions.

10.3. Possibility of Hazardous Reactions

Hazardous polymerisation does not occur.

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10.4. Conditions to Avoid

Keep away from heat

10.5. Incompatible Materials

Strong acids. Strong oxidising agents. Strong reducing agents.

10.6. Hazardous Decomposition Products

Carbon oxides

SECTION 11: Toxicological information

General Information

Occupational exposure to the substance or mixture may cause adverse effects.

Information on likely routes of exposure

Inhalation	May cause allergy/asthma symptoms, throat irritation or breathing difficulties if inhaled
Skin Contact	May cause skin irritation
Eye Contact	May cause eye irritation
Ingestion	May cause irritation and malaise

11.1 Information on Toxicological Effects

Component	Species	Test Results	
Sodium Propionate (RTECS UF7525000)			
Acute Toxicity	Oral,LD50	mouse	6,332 mg/kg
	Dermal, LD50	rabbit	1,640 mg/kg
Skin Corrosion/Irritation		No information available.	
Germ Cell Mutagenicity		No information available.	
Carcinogenicity		Not classified as a carcinogen:	
Reproductive Toxicity		No information available.	
Teratogenicity		No information available.	
Specific Target Organ Toxicity		No information available.	
Neurotoxicity		No information available.	
Other		No other specific health impact noted.	

Sodium Azide (RTECS VY8050000)			
Acute Toxicity	Oral,LD50	rat	27 mg/kg
	Dermal, LD50	rabbit	20 mg/kg
Skin Corrosion/Irritation		Rabbit rabbit	mild skin irritation at 24 hr severe eye irritation
Germ Cell Mutagenicity		No information available.	
Carcinogenicity		Not classified as a carcinogen:	
Reproductive Toxicity		No information available.	
Teratogenicity		No information available.	
Specific Target Organ Toxicity		No information available.	
Neurotoxicity		No information available.	
Other		No other specific health impact noted.	

Triton X-100 (RTECS MD0907700)			
Acute Toxicity	Oral,LD50	rat	500 mg/kg
	Dermal, LD50	rabbit	8,000 mg/kg
Skin Corrosion/Irritation		Rabbit rabbit	mild skin irritation at 24 hr severe eye irritation
Germ Cell Mutagenicity		No information available.	

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Carcinogenicity	Not classified as a carcinogen:	
Reproductive Toxicity	No information available.	
Teratogenicity	No information available.	
Specific Target Organ Toxicity	No information available.	
Neurotoxicity	No information available.	
Other	No other specific health impact noted.	

Note: The health effects above are based on an extrapolation of the data on the pure product ingredient. To the best of our knowledge, no health effects have been identified for the product mixture under normal working conditions.

Section 12: Ecological Information

12.1 Toxicity

Component	Species	Test Results
Sodium Azide		
Aquatic	Algae, EC50	Pseudokirchnerella subcapitata 0.35 mg/L, 96 hours
	Fish, LC50	Fish 5.7 mg/L, 96 hours

12.2 Persistence and degradability

No data is available.

12.3 Bioaccumulative potential

No data is available.

12.4 Mobility in soil

No data is available.

12.5 Results of PBT and vPvB assessment

Not a PBT or vPVP substance or mixture.

12.6 Other Adverse Effects

The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

SECTION 13: Disposal considerations

Waste treatment methods

Residual waste	Dispose in compliance with all federal, state and local regulations.
Contaminated packaging	Empty containers should be disposed of by an approved waste handler.
EU Waste Code	Waste code should be assigned in discussion between the user and the approved waste handler.
Disposal Information	This product contains a small amount of sodium azide which can react with copper, lead and brass plumbing systems and form potentially explosive metal azides. Flush drains with a large volume of water to prevent azide build-up.

SECTION 14: Transport information

ADR	Not regulated as dangerous goods.
RID	Not regulated as dangerous goods.
AND	Not regulated as dangerous goods.
IATA	Not regulated as dangerous goods.
IMDG	Not regulated as dangerous goods.

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SECTION 15: Regulatory information

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

EU Regulations

Regulation (EC) No. 2024/590 on substances that deplete the ozone layer, Annex I and II, as amended

Not listed.

Regulation (EC) No. 2019/10214 On persistent organic pollutants, Annex I as amended

Not listed.

Regulation (EC) No. 649/2012 concerning the export and import of hazardous chemicals, Annex I, part 1 as amended

Not listed.

Regulation (EC) No. 649/2012 concerning the export and import of dangerous chemicals, Annex I, part 2 as amended

Not listed.

Regulation (EC) No. 649/2012 concerning the export and import of dangerous chemicals, Annex I, part 3 as amended

Not listed.

Regulation (EC) No. 649/20128 concerning the export and import of dangerous chemicals, Annex V as amended

Not listed.

Regulation (EC) No. 166/2006 Annex II Pollutant Release and Transfer Registry, as amended

Not listed.

Regulation (EC) No. 1907/2006, REACH Article 59(10) Candidate List as currently published by ECHA

Not listed.

Authorisations

Regulation (EC) No. 1907/2006, REACH Annex XIV Substances subject to authorization, as amended.

Not listed.

Restrictions on Use

Regulation (EC) No. 1907/2006, REACH Annex XVII Substances subject to restriction on marketing and use as amended.

Not listed.

Directive 2004/37/EC: on the protection of workers from the risks related to exposure to carcinogens and mutagens at work, as amended.

Not listed.

Directive 92/85/EEC: on the safety and health of pregnant workers and workers who have recently given birth or are breastfeeding, as amended.

Not listed.

Other EU regulations

Directive 2012/18/EU on major accident hazards involving dangerous substances.

Sodium azide (CAS 26628-22-8)

Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.

Sodium azide (CAS 26628-22-8)

Directive 94/33/EC on the protection of young people at work

Sodium azide (CAS 26628-22-8)

Other Regulations

The product is classified and labelled in accordance with Regulation (EC)

1272/2008 (CLP Regulation) as amended and respective national laws implementing EC directives. This Safety Data Sheet complies with the requirements of Regulation (EC) No 1907/2006.

In the European Union this product is regulated under Regulation (EU) 2017/746 on In Vitro Diagnostic Medical Devices.

National Regulations

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This product has not been classified as dangerous according to the legislation in force.

TSCA

CAS# 26628-22-8 is listed on the TSCA inventory

CAS# 137-40-6 is listed on the TSCA inventory

CAS# 9002-93-1 is listed on the TSCA inventory

TSCA Significant New Use

None of the chemicals in this material have a SNUR under TSCA

Health & Safety Reporting List

None of the chemicals are on the Health & Safety Reporting List

Chemical Test Rules

None of the chemicals in this product are under a Chemical Test Rule.

Section 12b

None of the chemicals are listed under TSCA Section 12b

SARA

CERCLA Hazardous Substances and Corresponding RQs

CAS# 26628-22-8: 1000 lb final RQ; 454 kg final RQ

SARA Section 302 Extremely Hazardous Substances

CAS# 26628-22-8: 500 lb TPQ (This material is a reactive solid. The TPQ does not default to 10000 pounds for non-powder, non-molten, non-solvent form)

SARA Codes

CAS# 26628-22-8: acute, chronic, reactive

CAS# 9002-93-1: acute, chronic

Section 313

This material contains Sodium Azide (CAS#26628-22-8) but not in a high enough concentration to be reportable under Section 313 of SARA Title III and 40 CFR Part 372

Clean Air Act

This material does not contain any hazardous air pollutants.

This material does not contain any Class 1 Ozone depleters.

This material does not contain any Class 2 Ozone depleters.

Clean Water Act

None of the chemicals in this product are listed as Hazardous Substances under the CWA. None of the chemicals in this product are listed as Priority Pollutants under the CWA. None of the chemicals in this product are listed as Toxic Pollutants under the CWA.

OSHA

None of the chemicals in this product are considered highly hazardous by OSHA.

STATE

Sodium azide can be found on the following state right to know lists: California, New Jersey, Pennsylvania, Minnesota, Massachusetts.

California No Significant Risk Level: None of the chemicals in this product are listed.

Canada

CAS# 26628-22-8 is listed on Canada's DSL List and has a WHMIS classification of D1A, D2B, F.

CAS# 9002-93-1 is listed on Canada's DSL List and has a WHMIS classification of D2B.

CAS# 26628-22-8 is listed on Canada's Ingredient Disclosure List.

CAS# 9002-93-1 is listed on Canada's Ingredient Disclosure List.

Note: The regulatory information above is based on the information available for the pure product ingredient, not the finished product.

SECTION 16: Other information

16a. Indication of where changes have been made to the previous version of the safety data sheet

Revisions of this document

This is Revision 4 of this document.

Changes in all sections.

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16b. Legend to abbreviations and acronyms used in the safety data sheet

DNEL: Derived No-Effect Level.

PNEC: Predicted No-Effect Concentration.

LD50: Lethal Dose, 50%

16c. Key literature references and sources for data

References

IARC Monographs. Overall Evaluation of Carcinogenicity

HSDB® - Hazardous Substances Data Bank

Full texts for Regulations mentioned in this Safety Data Sheet

R22	Harmful if swallowed
R28	Very toxic if swallowed
R32	Contact with acids liberates very toxic gas.
R50/53	Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
H300	Fatal if swallowed.
H310	Fatal in contact with skin.
H400	Very toxic to aquatic life. H410 Very toxic to aquatic life with long lasting effects.

16d. Methods of evaluating information referred to in 1272/2008 Article 9 which was used for the purpose of classification

The classification for health and environmental hazards is derived by a combination of calculation methods and test data, if available.

16e. Training Information

Follow training instructions when handling this material.

TECO GmbH provides the information in this data sheet in good faith, declaring it is up to date at time of revision. However, this document is intended only as a guide for professional use, according to the intended purposes of the product. It does not represent a guarantee for the properties of the product described in terms of the legal warranty regulations.