

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 FIB
Article number A0511-020, A0511-050

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

Identified uses For professional users only
Uses Advised Against Not known

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

Regulation (EC) No.1272/2008 (CLP) Not classified as dangerous for supply/use

2.2. Label elements

According to Regulation (EC) No. 1272/2008 (CLP)
Product Name Fibrinogen Reagent
Hazard pictogram (s) Not applicable

2.3. Other hazards

None know.

2.4. Additional Information

The usual precautions for handling chemicals should be observed.
Contains animal derived material – potentially biohazardous

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable.

3.2. Mixtures

HAZARDOUS INGREDIENT(S)	CAS No.	EC No. / REACH Registration No.	%W/W	Hazard Statement(s)	Hazard Pictogram(s)
Sodium azide	26628-22-8	EC 247-852-1	< 0.1	Acute Tox. 2 300 Aquatic Acute 1 H400 Aquatic Chronic 1 H410	GHS06 GHS09

HAZARDOUS INGREDIENT(S)	CAS No.	Specific Concentration Limit	M-factor	ATE
Sodium azide	26628-22-8			Acute Tox. 2 (H300): 5

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

Safety Data Sheet

TECO

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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.

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. References 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.

Safety Data Sheet

TECO

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SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 Occupational Exposure Limits.

Occupational Exposure Limits

SUBSTANCE.	CAS No.	LTCL (8 hr TWA ppm)	LTCL (8 hr TWA mg/m ³)	STCL (ppm)	STCL (mg/m ³)	Note
Sodium azide (as NaN ₃)	26628-22-8		0.1		0.3	Sk

Region	Source
United Kingdom	UK Workplace Exposure Limits EH40/2005 (Fourth edition, published 2020)

Remark	Notes
Sk	Can be absorbed through the skin. The assigned substances are those for which there are concerns that dermal absorption will lead to systemic toxicity.

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.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

(a) Physical state	solid (lyoph.)
(b) Colour	White
(c) Odour	Odorless
(d) Melting point/freezing point	Not known.
(e) Boiling point or initial boiling point and boiling range	Not applicable.
(f) Flammability	Not known.
(g) Lower and upper explosion limit	Not known.
(h) Flash point	Not applicable.
(i) Auto-ignition temperature	Not known.
(j) Decomposition temperature	Not known.
(k) pH	Not known.
(l) Kinematic viscosity	Not known.
(m) Solubility	Solubility (Water): readily miscible. Solubility (Other): Not known
(n) Partition coefficient: n-octanol/water (log value)	Not known.
(o) Vapour pressure	Not known.
(p) Density and/or relative density	Not known.
(q) Relative vapour density	Not known.
(r) Particle characteristics	Not known.

9.2. Other information

None.

Safety Data Sheet

TECO

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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	Calculation method : Harmful if swallowed. Calculation method : Calculated acute toxicity estimate (ATE) Calc ATE - 500
Acute toxicity - Skin Contact	Calculation method : Not classified.
Acute toxicity - Inhalation	Calculation method : Not classified.
Skin corrosion/irritation	Calculation method : Not classified.
Serious eye damage/irritation	Calculation method : Not classified.
Skin sensitization data	Calculation method : Not classified.
Respiratory sensitization data	Calculation method : Not classified.
Germ cell mutagenicity	Calculation method : Not classified.
Carcinogenicity	Calculation method : Not classified.
Reproductive toxicity	Calculation method : Not classified.
Lactation	Not classified.
STOT - single exposure	Calculation method : Not classified.
STOT - repeated exposure	Calculation method : Not classified.
Aspiration hazard	Calculation method : Not classified.

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.

Safety Data Sheet

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12.6. Endocrine disrupting properties

None known

12.7. Other toxic 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

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.

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 - Authorizations and/or Restrictions on Use

Candidate List of Substances of Very High Concern for Authorization	Not listed
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REACH: ANNEX XIV list of substances subject to authorization	Not listed
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REACH: Annex XVII Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles	sodium azide (26628-22-8)
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Community Rolling Action Plan (CoRAP)	Not listed.
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Regulation (EC) N° 2019/1021 of the European Parliament and of the Council on persistent organic pollutants	Not listed.
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Regulation (EC) N° 1005/2009 on substances that deplete the ozone layer	Not listed.
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Regulation (EU) N° 649/2012 of the European Parliament and of the Council concerning the export and import of hazardous chemicals	Not listed
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National regulations

Other	Not known.
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15.2. Chemical safety assessment

A REACH chemical safety assessment has not been carried out.

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 3 of this document.
Changes in all sections.

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

Explanations of the abbreviations and Acronyms:

Hazard Pictogram(s)	GHS06: Skull and crossbones GHS09: Environment
Hazard classification (s)	Acute Tox. 2: Acute toxicity, Category 2 Aquatic Acute 1: Hazardous to the aquatic environment, Acute, Category 1 Aquatic Chronic 1: Hazardous to the aquatic environment, Chronic, Category 1
Hazard Statement(s)	H300: Fatal if swallowed. 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, Authorization and Restriction of Chemicals STEL : Short term exposure limit STOT : Specific Target Organ Toxicity vPvB : very Persistent and very Bioaccumulative

16c. Key literature references and sources for data

Sources for data

Regulation (EC) No. 1272/2008 (CLP).

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.