

Safety Data Sheet

Technochrom anti-Xa



SDS No. 0800.01

p 1/7 EN

Temp.: TF0366.01
Alt. 01 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.	Technochrom anti-Xa	~ 80 T.	REF 5340250
Product Components	Reagent 1	Tris-EDTA buffer	1 x 20 mL
	Reagent 2	Bovine Factor Xa	1 x 4 mL
	Reagent 3	Chromogenic substrate	1 x 4 mL

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

	Regulation (EC) No. 1272/2008 (CLP)
Reagent 1 Tris-EDTA buffer	Not classified as dangerous for supply/use
Reagent 2 Bovine Factor Xa	Not classified as dangerous for supply/use
Reagent 3 Chromogenic substrate	Not classified as dangerous for supply/use

2.2 Label elements

Product Name	According to Regulation (EC) No. 1272/2008 (CLP) Technochrom anti-Xa
Hazard Pictogram(s)	None.

2.3 Other hazards

None known.

2.4 Additional Information

Reagent 1	Tris-EDTA buffer	The usual precautions for handling chemicals should be observed.
Reagent 2	Bovine Factor Xa	Contains animal derived material – potentially biohazardous
Reagent 3	Chromogenic substrate	The usual precautions for handling chemicals should be observed.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Not applicable.

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3.2 Mixtures

Component	HAZARDOUS INGREDIENT(S)	CAS No.	EC No. / REACH Registration No.	%W/W	Hazard Statement(s)	Hazard Pictogram(s)	
Reagent 1	Tris-EDTA buffer	Sodium azide	26628-22-8	EC 247-852-1	< 0.1	Acute Tox. 2 H300 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.

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 Reference to other sections

See Also Section 8, 13.

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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

Occupational Exposure Limits

SUBSTANCE.	CAS No.	LTEL (8 hr TWA ppm)	LTEL (8 hr TWA mg/m ³)	STEL (ppm)	STEL (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

Physical state

Reagent 1	Tris-EDTA buffer	liquid
Reagent 2	Bovine Factor Xa	solid (lyoph.)
Reagent 3	Chromogenic substrate	solid (lyoph.)

Colour

Reagent 1	Tris-EDTA buffer	without colour
Reagent 2	Bovine Factor Xa	white
Reagent 3	Chromogenic substrate	without colour

Odour – all components odourless

Melting point/freezing point Not known.

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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
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.

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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

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

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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 Not listed

High Concern for Authorisation

REACH: ANNEX XIV list of Not listed

substances subject to authorisation

REACH: Annex XVII Restrictions on sodium azide (26628-22-8)

the manufacture, placing on the

market and use of certain dangerous

substances, mixtures and articles

Community Rolling Action Plan Not listed

(CoRAP)

Regulation (EC) N° 2019/1021 of Not listed

the European Parliament and of the

Council on persistent organic

pollutants

Regulation (EC) N° 1005/2009 on Not listed

substances that deplete the ozone

layer

Regulation (EU) N° 649/2012 of the Not listed

European Parliament and of the

Council concerning the export and

import of hazardous chemicals

National regulations

Other Not known.

15.2 Chemical Safety Assessment

A REACH chemical safety assessment has not been carried out.

SECTION 16: OTHER INFORMATION

Date of Issue 2023-09-21 (replaces SDS No. 323.03 from 2017-05-18)

Date of Revision n.a.

LEGEND

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, Authorisation and Restriction of Chemicals

STEL : Short term exposure limit

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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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