

Safety Data Sheet

Technozym ADAMTS-13 INH



SDS No. RP00.02

p 1/7 EN

Temp.: TFD366.01
Att.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.	Technozym ADAMTS-13 INH	96 T.	REF 5450401
	Technozym ADAMTS-13 INH	48 T.	REF 5450451
Component 1	ELISA test strips protein coated	12 strips/6 strips	
Component 2	Calibrator Plasma (1 to 5)	1 x 0.5 mL each, lyoph.	
Component 3	Control Plasma (high and low)	1 x 0.5 mL each, lyoph.	
Component 4	Incubation buffer	1 x 90 mL	
Component 5	Wash buffer concentrate	1 x 80 mL	
Component 6	Conjugate	1 x 0.3 mL	
Component 7	TMB substrate	1 x 12 mL	
Component 8	Stop Solution	1 x 12 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)

Component 8 (Stop solution) Classified as skin and eye irritant Cat. 2

2.2 Label elements

Product Name	According to Regulation (EC) No. 1272/2008 (CLP) Stop Solution (component 8)
Hazard Pictogram(s)	 GHS07
Signal Word(s)	Warning
Hazard Statement(s)	H315: causes skin irritation H319 .causes serious eye irritation
Precautionary Statement(s)	P264 wash hands thoroughly after handling

2.3 Other hazards

None known.

Safety Data Sheet

Technozym ADAMTS-13 INH



SDS No. RP00.02
p 2/7 EN

Temp.: TFD366.01
Art.01 to D00068

2.4 Additional Information

Components 2 and 3

The usual precautions for handling chemicals should be observed..
Contain human derived material - potentially biohazardous
For full text of H/P Statements see section 16.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Not applicable.

3.2 Mixtures

TMB substrate (component 7)

HAZARDOUS INGREDIENT(S)	CAS No.	EC No. / REACH Registration No.	%W/W	Hazard Statement(s)	Hazard Pictogram(s)
3,3',5,5'-Tetramethyl-benzidine	54827-17-7	259-364-6	< 0.02%	Acute Tox. 4; Carc. 2; Aquatic Chronic 4; H302, H351, H413	GHS07

Stop Solution (component 8)

HAZARDOUS INGREDIENT(S)	CAS No.	EC No. / REACH Registration No.	%W/W	Hazard Statement(s)	Hazard Pictogram(s)
Sulfuric acid %	7664-93-9	231-639-5/01- 2119458838-20-xxxx	1%<C<5%	Skin Corr. 1A H314	GHS05

HAZARDOUS INGREDIENT(S)	CAS No.	Specific Concentration Limit	M-factor	ATE	
sulphuric acid ...%	7664-93-9	Skin Corr. 1A	C>= 15.00 <= 100.00		
		Skin Irrit. 2	C>= 5.00 < 15.00		
		Eye Irrit. 2	C>= 5.00 < 15.00		

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.

Safety Data Sheet

Technozym ADAMTS-13 INH



SDS No. RP00.02
p 3/7 EN

Temp.: TFD366.01
At: 01 to D00068

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.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Physical state

Component 1	ELISA test strips protein coated	solid
Component 2	Calibrator Plasma (1 to 5)	solid
Component 3	Control Plasma (high and low)	solid
Component 4	Incubation buffer	liquid
Component 5	Wash buffer concentrate	liquid
Component 6	Conjugate	liquid

Safety Data Sheet



Temp.: TFD366.01
Att.01 to D00068

Technozym ADAMTS-13 INH

SDS No. RP00.02

p 4/7 EN

Component 7	TMB substrate	liquid
Component 8	Stop Solution	liquid
Colour		
Component 1	ELISA test strips protein coated	Without colour
Component 2	Calibrator Plasma (1 to 5)	White-Yellowish
Component 3	Control Plasma (high and low)	White-Yellowish
Component 4	Incubation buffer	Blue
Component 5	Wash buffer concentrate	Without colour
Component 6	Conjugate	Blue
Component 7	TMB substrate	Without colour
Component 8	Stop Solution	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

Safety Data Sheet

Technozym ADAMTS-13 INH



SDS No. RP00.02
p 5/7 EN

Temp.: TFD366.01
Art. 01 to D00068

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

Safety Data Sheet

Technozym ADAMTS-13 INH



SDS No. RP00.02
p 6/7 EN

Temp.: TFD366.01
At: 01 to D00068

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 - 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	sulphuric acid ... % (7664-93-9)
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.

15.2 Chemical Safety Assessment

A REACH chemical safety assessment has not been carried out.

SECTION 16: OTHER INFORMATION

Date of Issue 2023-09-05 (replaces RP00E.01_SDB, issued 2019-03-21)
Date of Revision 2024-02-28, another package size was added

LEGEND

Hazard Pictogram(s)	GHS05: Corrosion, GHS07: Health Hazard
Hazard classification	Skin Corr. 1A : Skin corrosion/irritation, Category 1A, Skin Irrit. 2: Skin irritation, Category 2
Hazard Statement(s)	H314: Causes severe skin burns and eye damage. H315: causes skin irritation H319 .causes serious eye irritation
Precautionary Statement(s)	P264 wash hands thoroughly after handling

Safety Data Sheet

Technozym ADAMTS-13 INH



SDS No. RP00.02

p 7/7 EN

Temp.: TFD366.01
Att 01 to D00068

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)

Disclaimers

Information contained in this publication or as otherwise supplied to users is believed to be accurate and is given in good faith, but it is for the Users to satisfy themselves of the suitability of the product for their own particular purpose. Technoclone Herstellung von Diagnostika und Arzneimitteln GmbH gives no warranty as to the fitness of the product for any particular purpose and any implied warranty or condition (statutory or otherwise) is excluded except to the extent that exclusion is prevented by law. Technoclone Herstellung von Diagnostika und Arzneimitteln GmbH accepts no liability for loss or damage (other than that arising from death or personal injury caused by defective product, if proved), resulting from reliance on this information. Freedom under Patents, Copyright and Designs cannot be assumed.