

# Safety Data Sheet

## Technozym ADAMTS-13 Antigen



SDS No. RR00.01

p 1/7 EN

Temp.: TFD366.01  
Art. 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 Antigen	96 T.	REF 5450601
Component 1	ELISA test strips antibody coated	12 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.

#### 2.4 Additional Information

The usual precautions for handling chemicals should be observed..

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Components 2 and 3

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'-Tetramethylbenzidine	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.

#### 5.3 Advice for firefighters

As appropriate for surrounding fire.

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### 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 antibody 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
Component 7	TMB substrate	liquid
Component 8	Stop Solution	liquid

##### Colour

Component 1	ELISA test strips antibody coated	Without colour
Component 2	Calibrator Plasma (1 to 5)	White-Yellowish

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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
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

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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

### 14.4 Packing group

Not applicable

### 14.5 Environmental hazards

Not classified as a Marine Pollutant.

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### 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 RR00E.01\_SDB, issued 2019-03-21)  
Date of Revision n.a.

### 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
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

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### 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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