

Safety Data Sheet

Technozym ADAMTS-13 Activity



SDS No. RU00.01

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 Activity	96 T.	REF 5450701
Component 1	ELISA test strips, antibody coated	12 strips	
Component 2	Calibrator Plasma (1 to 6)	1 x 0.5 mL each, lyoph.	
Component 3	Control Plasma (high and low)	1 x 0.5 mL each, lyoph.	
Component 4	Reaction buffer	1 x 30 mL	
Component 5	Wash buffer concentrate	1 x 53 mL	
Component 6	Conjugate	1 x 12 mL	
Component 7	TMB substrate	1 x 12 mL	
Component 8	Stop Solution	1 x 12 mL	
Component 9	GST-vWF73 Substrate	2 x 6 mL, lyoph.	

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.

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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.

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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.

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 6)	solid,lyoph.
Component 3	Control Plasma (high and low)	solid,lyoph.
Component 4	Reaction buffer	liquid
Component 5	Wash buffer concentrate	liquid

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Component 6	Conjugate	liquid
Component 7	TMB substrate	liquid
Component 8	Stop Solution	liquid
Component 9	GST-vWF73 Substrate	solid,lyoph.

Colour

Component 1	ELISA test strips, antibody coated	Without colour
Component 2	Calibrator Plasma (1 to 6)	White-Yellowish
Component 3	Control Plasma (high and low)	White-Yellowish
Component 4	Reaction buffer	Without colour
Component 5	Wash buffer concentrate	Without colour
Component 6	Conjugate	Without colour
Component 7	TMB substrate	Without colour
Component 8	Stop Solution	Without colour
Component 9	GST-vWF73 Substrate	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

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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

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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 RU00E.02_SDB)
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

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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 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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