Safety Data Sheet TF0366.01 to D00068 Temp.: Att 01 t SDS No. 7QT00.01 **TECHNOZYM ADAMTS13 CON Set** p 1/6 ΕN 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 ADAMTS13 CON Set 5 x 0.5 ml RFF 5450563 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) Not classified as dangerous for supply/use

2.2 Label elements

2.3 Other hazards	
Hazard Pictogram(s)	None.
Product Name	TECHNOZYM ADAMTS13 CON Set
	According to Regulation (EC) No. 1272/2008 (CLP)

None known.

2.4 Additional Information

Contains human derived material - potentially biohazardous

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Not applicable.

3.2 Mixtures

Product does not contain any hazardous ingredients.

Contains no non-classified vPvB substances or substances with a Union workplace exposure limit.

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.

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Skin Contact Eye Contact Ingestion Wash skin with water. Flush eyes with water for at least 15 minutes. 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 MEASUR	RES	
5.1 Extinguishing media		
Suitable Extinguishing media Unsuitable extinguishing media	As appropriate for surrounding fire. 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, prote	ctive 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 STORA	GE	
7.1 Precautions for safe handling	Ig	
	Not known.	
7.2 Conditions for safe storage,	including any incompatibilities	
Storage temperature Storage life Incompatible materials	2°C to 8°C Stable under normal conditions. 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 Ensure adequate ventilation. controls

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8.2.2. Personal protection equipment

Eye Protection
Skin protectionWear eye protection with side protection (EN166).
Gloves recommended
Normally no personal respiratory protection is necessary.
None known.8.2.3. Environmental Exposure
ControlsDo 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	solid
Colour	white-yellowish
Odour	odourless
Melting point/freezing point	Not known.
Boiling point or initial boiling point	Not applicable.
and boiling range	
Flammability	Not known.
Lower and upper explosion limit	Not known.
Flash Point	Not applicable.
Auto-ignition temperature	Not known.
Decomposition Temperature	Not known.
рН	Not known.
Kinematic Viscosity	Not known.
Solubility	Solubility (Water) : readily miscible.
	Solubility (Other) : Not known
Partition coefficient n-octanol/water	Not known.
(log value)	
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

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Acute toxicity - Skin Contact Acute toxicity - Inhalation Skin corrosion/irritation Serious eye damage/irritation Skin sensitization data Respiratory sensitization data Germ cell mutagenicity Carcinogenicity Reproductive toxicity Lactation STOT - single exposure STOT - repeated exposure Aspiration hazard Low acute toxicity Low acute toxicity Non-irritant Non-irritant Not classified Not classified There is no evidence of mutagenic potential. No evidence of carcinogenicity. Not classified Not classified Not classified Not classified Not classified Not classified Not classified

11.2 Information on other hazards

Not known.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Toxicity - Aq	uatic invertebrates	Low toxicity	to invertebrates.
Toxicity - Fis	h	Low toxicity	to fish.
Toxicity - Alg	jae	Low toxicity	to algae.
Toxicity - Se	diment Compartment	Not classified	1.
Toxicity - Te	rrestrial Compartment	Not classified	1.

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 Not listed High Concern for Authorisation REACH: ANNEX XIV list of Not listed substances subject to authorisation REACH: Annex XVII Restrictions on Not listed the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles Community Rolling Action Plan Not listed (CoRAP) Regulation (EC) Nº 850/2004 of the Not listed 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) Nº 649/2012 of the Not listed European Parliament and of the Council concerning the export and import of hazardous chemicals

National regulations

Other

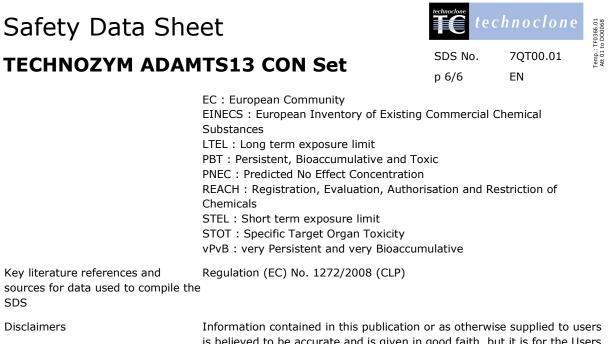
Not known.

15.2 Chemical Safety Assessment

CECTION 1C. OTHER INFORMATIO

A REACH chemical safety assessment has not been carried out.

SECTION 16: OTHER INFORMATION		
Date of Issue Date of Revision	2023-09-05 (replaces SDS 123.02 from 2017-05-05) n.a.	
LEGEND		
Hazard Pictogram(s Precautionary State	,	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



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