Safety Data Sheet					technoclone	techno	clone	366.01 20068
<b>TECHNOFLUOR ADAMTS13 Activity</b>					SDS No. p 1/7	. FAOC EN	).01	Temp.: TF0366.01 Att 01 to D00068
ACCO	ORDING TO EC	C-REGULATIONS	1907/200	06 (REACH), 1272/2	2008 (CL	P) & 2020/	878	
SECTION 1: IDEN	ITIFICATION C	OF THE SUBSTAN	CE/MIXT	URE AND OF THE C	OMPANY/	UNDERTA	KING	
1.1 Product ide	entifier							
Product Name/Re	eference No.	TECHNOFLUOR A	ADAMTS1	3 Activity		25 T.	REF 58001	L00
Product Compone	ents	•		LUOR ADAMTS13 E LUOR ADAMTS13 S		2 x 3 mL 2 x 1 mL		
1.2 Relevant id	entified uses	s of the substan	ice or mi	ixture and uses a	dvised a	gainst		
Identified Use(s) Uses Advised Aga	ainst	For profess Not known		ers only				
1.3 Details of t	he supplier o	of the safety dat	ta sheet					
Manufacturer								
Company IdentificationTechnoclone Herstellung von Diagnostika und Arzneimitteln GmbAddress of ManufacturerBrunner Strasse 671230 ViennaAustriaPostal code1230					n GmbH			
Telephone:		+43 1 863						
Fax E-mail		+43 1 863 products@		one.com				
Office hours		8:00 - 16:						
1.4 Emergency	telephone n	umber						
Emergency Phone	e No.	+43 1 863						
Contact National response	e center	products@	technoclo	one.com				
Address		NHS Direct	t					
Emergency Phone	e No.	+44 111						
SECTION 2: HAZA	ARDS IDENTIF	ICATION						
2.1 Classification	on of the sub	stance or mixt	ure					
		R ADAMTS13 But R ADAMTS13 Sul		Regulation (EC) N Not classified as d Not classified as d	langerous	for supply	/use	
2.2 Label eleme	ents							
Product Name Hazard Pictogram	n(s)	-	-	ation (EC) No. 1272 MTS13 Activity	/2008 (C	LP)		
2.3 Other haza	rds							
		None know	/n.					
2.4 Additional	Information							
•	TECHNOFLUO	R ADAMTS13		al precautions for h	nandling o	chemicals s	should be	
Component 2	Buffer     observed.       Component 2     TECHNOFLUOR ADAMTS13     The usual precautions for observed.       Substrate     observed.			al precautions for h	nandling o	chemicals s	should be	
SECTION 3: COM	POSITION/INF	ORMATION ON I	NGREDIE	INTS				
3.1 Substances	;							
		Not applica	able.					

#### 3.2 Mixtures



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Component		HAZARDOUS INGREDIENT(S)	CAS No.	EC No. / REACH Registration No.	%W/W	Hazard Statement(s)	Hazard Pictogram(s)
	TECHNOFLUOR ADAMTS13 Buffer	Bis-Tris	6976-37-0	Reach No: 01-2120768016 - 54-XXXX	< 0,5 %	Serious eye damage Cat 1, H318*	GHS05
		CaCl <sub>2</sub> .2H <sub>2</sub> O	1003504-8	233-140-8/ 01- 2119494219-28- xxxx	< 0,5 %	Eye irritiant Cat 2, H319*	GHS07
		NaN3	26628-22- 8	247-852-1/01- 2119457019-37- xxxx	< 0,05 %	Acute Oral Toxicity Cat 2, H300*; Acute dermal toxicity Cat 1, H310*; STOT RE 2, H373*; aquatic chronic tox. Cat 1, H410*	GHS06 GHS08 GHS09
	TECHNOFLUOR ADAMTS13 Substrate	Bis-Tris	6976-37-0	Reach No: 01-2120768016 - 54-XXXX	< 0,5 %	Serious eye damage Cat 1, H318*	GHS05
		CaCl <sub>2</sub> .2H <sub>2</sub> O	1003504-8	233-140-8/ 01- 2119494219-28- xxxx	< 0,5 %	Eye irritiant Cat 2, H319*	GHS07

HAZARDOUS INGREDIENT(S)	CAS No.	Specific concentration limit	M-factor	ATE
NaN₃	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 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, 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

Occupational	Exposure	Limits
--------------	----------	--------

SUBSTANCE.	CAS No.	LTEL (8 hr TWA ppm)	LTEL (8 hr TWA mg/m³)	STEL (ppm)	STEL (mg/m³)	Note	
Sodium azide (as NaN3)	26628-22-8		0.1		0.3	Sk	
Region	Source UK Workplace Exposure I	imits EH40/2005	(Fourth edition, publis	shed 2020)			
Remark	Remark Notes 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	e controls						
8.2.1. Approp controls 8.2.2. Person equipment	oriate engineering al protection	Ensure ad	equate ventilatio	n.			
F	Eye Protectic Skin protectic Respiratory protectic Thermal hazaro nmental Exposure	on Gloves rec on Normally i ds None know	no personal resp	iratory protec	tion is necess		

#### Controls

#### SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

#### 9.1 Information on basic physical and chemical properties

Physical state		
Component 1	TECHNOFLUOR ADAMTS13 Buffer	liquid
Component 2	TECHNOFLUOR ADAMTS13 Substrate	solid (lyoph.)

SDS No.FA00.01p 4/7kNColourTECHNOFLUOR ADAMTS13 Bufferwithout colourComponent 1TECHNOFLUOR ADAMTS13 Subfrerwithout colourComponent 2TECHNOFLUOR ADAMTS13 Substratewithout colourOdour - all componentsodourless	Safety Data Sheet	technoclone technoclone technoclone	chnoclone	
Colourp 4//ENComponent 1TECHNOFLUOR ADAMTS13 Bufferwithout colourComponent 2TECHNOFLUOR ADAMTS13 Substratewithout colourOdour - all componentsodourlessMelting point/freezing pointNot known.Boiling point or initial boiling point and boiling rangeNot applicable.FlammabilityNot known.Lower and upper explosion limitNot known.Flash PointNot known.Auto-ignition temperatureNot known.Decomposition TemperatureNot known.pHNot known.SolubilitySolubility (Water) : readily miscible.SolubilitySolubility (Other) : Not knownPartition coefficient n-octanol/water (log value)Not known.Vapour pressureNot known.Density and/or relative densityNot known.Relative vapour densityNot known.	TECHNOELLIOD ADAMTS12 A	SDS No.	FA00.01	
Component 1TECHNOFLUOR ADAMTS13 Bufferwithout colourComponent 2TECHNOFLUOR ADAMTS13 Substratewithout colourOdour - all componentsodourlessMelting point/freezing pointNot known.Boiling point or initial boiling point and boiling rangeNot applicable.FlammabilityNot known.Lower and upper explosion limitNot known.Flash PointNot known.Auto-ignition temperatureNot known.Decomposition TemperatureNot known.pHNot known.Kinematic ViscosityNot known.SolubilitySolubility (Water) : readily miscible. Solubility (Other) : Not knownPartition coefficient n-octanol/water (log value)Not known.Vapour pressureNot known.Density and/or relative densityNot known.Relative vapour densityNot known.	TECHNOFLOOR ADAMISIS A		p 4/7	EN
	Component 1 TECHNOFLUOR ADAMTS13 Buffer Component 2 TECHNOFLUOR ADAMTS13 Substrate Odour – all components Melting point/freezing point Boiling point or initial boiling point and boiling range Flammability Lower and upper explosion limit Flash Point Auto-ignition temperature Decomposition Temperature pH Kinematic Viscosity Solubility Partition coefficient n-octanol/water (log value) Vapour pressure Density and/or relative density Relative vapour density	without colour odourless Not known. Not applicable. Not known. Not known. Not known. Not known. Not known. Solubility (Water Solubility (Other) Not known. Not known. Not known. Not known. Not known. Not known. Not known.	, ,	
		NOU KHOWH.		

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#### 9.2 Other information

None.

SECTI	SECTION 10: STABILITY AND REACTIVITY				
10.1	0.1 Reactivity				
	None anticipated.				
10.2	0.2 Chemical Stability				
	Stable under normal conditions.				
10.3	0.3 Possibility of hazardous reactions				
	No hazardous reactions known if used for	or its intended purpose.			
10.4	0.4 Conditions to avoid				
	None anticipated.				
10.5	0.5 Incompatible materials				
	Not known.				
10.6	0.6 Hazardous decomposition products				
	No hazardous decomposition products k	nown.			
SECTI	ECTION 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.

#### 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.

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#### 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

#### 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 Ver High Concern for Authorisation 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 dangerou substances, mixtures and articles	Bis-Tris (CAS 6976-37-0), CaCl2.2H2O (CAS 1003504-8), NaN3 (CAS 26628-22-8)
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	e 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 Date of Revision	2024-03-13 (replaces FA00E.01_SDB from 2020-09-04) n.a.			
LEGEND				
Hazard Pictogram(s)	GHS05: Corrosion GHS06: Acute Toxicity GHS07: Harmful GHS08: Serious Health Hazard GHS09: Environmental Hazard			
Hazard classification (s	Acute Oral Tox. 2:acute oral toxicity, category 2Serious Eye dam 1:serious eye damage, category 1Eye irritant 2:eye irritant, category 2Acute Derm. Tox.1:acute dermal toxicity, category 1STOT RE 2:specific target organ toxicity - repeated exposure, category 2Aquatic chronic tox. 1:hazardous to the aquatic environment (long-term (chronic)),category 1			
Hazard Statement(s) Precautionary	<ul> <li>H300: Fatal if swallowed</li> <li>H310: Fatal in contact with skin</li> <li>H318: Causes serious eye damage</li> <li>H319: Causes serious eye irritation</li> <li>H373: May cause damage to organs through prolonged or repeated exposure</li> <li>H410: Very toxic to aquatic life with long lasting effects</li> <li>P264: Wash hands thoroughly after handling.</li> </ul>			
Statement(s)	204. Wash hands thoroughly after handling.			



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Acronyms	<ul> <li>ATE : Acute Toxicity Estimate</li> <li>CAS : Chemical Abstracts Service</li> <li>CLP : Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures</li> <li>DNEL : Derived No Effect Level</li> <li>EC : European Community</li> <li>EINECS : European Inventory of Existing Commercial Chemical Substances</li> <li>LTEL : Long term exposure limit</li> <li>PBT : Persistent, Bioaccumulative and Toxic</li> <li>PNEC : Predicted No Effect Concentration</li> <li>REACH : Registration, Evaluation, Authorisation and Restriction of Chemicals</li> <li>STEL : Short term exposure limit</li> <li>STOT : Specific Target Organ Toxicity</li> <li>vPvB : very Persistent and very Bioaccumulative</li> </ul>
Key literature references and sources for data used to compile the SDS	Regulation (EC) No. 1272/2008 (CLP)
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