

Safety Data Sheet



Technozym vWF Antigen ELISA

SDS No. RA00.01

p 1/8 EN

Temp.: TFO 366.01
Alt: 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 vWF:Ag ELISA	96 T.	REF 5450201
Component 1	ELISA test strips coated with anti-vWF antibody	12 strips	
Component 2	Calibrator Plasma (1 to 5)	1 x y mL each, lyoph.	
Component 3	Control Plasma (high and low)	1 x y mL each, lyoph.	
Component 4	Incubation buffer	y x z mL	
Component 5	Wash buffer concentrate	y x z mL	
Component 6	Conjugate	y x z mL	
Component 7	TMB substrate	y x z mL	
Component 8	Stop Solution	y x z 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 4	Incubation Buffer	Skin Sens. 1A, Skin sensitization, category 1A
Component 8	Stop solution	Skin and Eye Irrit. 2, Skin and Eye Irritant, category 2

2.2 Label elements

Product Name	According to Regulation (EC) No. 1272/2008 (CLP) Incubation Buffer (component 4) Stop Solution (component 8)
Hazard Pictogram(s)	 GHS07
Signal Word(s)	Warning
Hazard Statement(s)	H315: causes skin irritation H317: May cause an allergic skin reaction H319 .causes serious eye irritation
Precautionary Statement(s)	P264 wash hands thoroughly after handling

2.3 Other hazards

None known.

Safety Data Sheet



Technozym vWF Antigen ELISA

SDS No. RA00.01

p 2/8 EN

Temp.: TFO 366.01
Art. 01 to D00068

2.4 Additional Information

All components The usual precautions for handling chemicals should be observed.

Component 2 Calibrator Plasma (1 to 5) Contain human derived material - potentially biohazardous

Component 3 Control Plasma (high and low) 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

Component	HAZARDOUS INGREDIENT(S)	CAS No.	EC No. / REACH Registration No.	%W/W	Hazard Statement(s)	Hazard Pictogram(s)	
Component 4	Incubation buffer	3(2H)-Isothiazolone, 5-chloro-2-methyl-, mixt. with 2-methyl-3(2H)-isothiazolone	55965-84-9	611-341-5	0.0015	Acute Tox. 3 H301 Acute Tox. 2 H310 Skin Corr. 1C H314 Skin Sens. 1A H317 Eye Dam. 1 H318 Acute Tox. 2 H330 Aquatic Acute 1 H400 Aquatic Chronic 1 H410	GHS05 GHS06 GHS07 GHS09
Component 7	TMB substrate	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
Component 8	Stop solution	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	
3(2H)-Isothiazolone, 5-chloro-2-methyl-, mixt. with 2-methyl-3(2H)-isothiazolone	55965-84-9	Skin Corr. 1C	C>= 0.60 <= 100.00	Aquatic Acute 1: 100 Aquatic Chronic 1: 100	Acute Tox. 3 (H301) : 100 Acute Tox. 2 (H310) : 50 Acute Tox. 2 (H330) : 0.500
		Skin Irrit. 2	C>= 0.06 < 0.60		
		Skin Sens. 1A	C>= 0.0015 <= 100.00		
		Eye Dam. 1	C>= 0.60 <= 100.00		
		Eye Irrit. 2	C>= 0.06 < 0.60		
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. Treat symptomatically.

Safety Data Sheet



Technozym vWF Antigen ELISA

SDS No. RA00.01
p 3/8 EN

Temp.: TFO 366.01
Art: 01 to D00068

Skin Contact	Wash skin with water. If skin irritation or rash occurs, get medical advice/attention.
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

Allergic contact dermatitis. Treat symptomatically.

4.3 Indication of any immediate medical attention and special treatment needed

IF exposed or concerned: Get medical advice/attention. 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.

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

This material and its container must be disposed of in a safe way.

6.3 Methods and material for containment and cleaning up

Sweep spilled substances into containers. Transfer to a container for disposal.

6.4 Reference to other sections

See Also Section 8, 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

None 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

Safety Data Sheet



Technozym vWF Antigen ELISA

SDS No. RA00.01
p 4/8 EN

Temp.: TFO 366.01
Att: 01 to D00068

Occupational Exposure Limits						
SUBSTANCE.	CAS No.	LTEL (8 hr TWA ppm)	LTEL (8 hr TWA mg/m ³)	STEL (ppm)	STEL (mg/m ³)	Note
Sulphuric acid (mist)	7664-93-9		0.05			(k)

Region	Source
United Kingdom	UK Workplace Exposure Limits EH40/2005 (Fourth edition, published 2020)

Remark	Notes
(k)	The mist is defined as the thoracic fraction

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 Spillages or uncontrolled discharges into watercourses must be alerted to the appropriate regulatory body.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Physical state

Component 1	ELISA test strips coated with anti-vWF antibody	Solid
Component 2	Calibrator Plasma (1 to 5)	Solid (lyoph.)
Component 3	Control Plasma (high and low)	Solid (lyoph.)
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 coated with Collagen III	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.

Safety Data Sheet



Technozym vWF Antigen ELISA

SDS No. RA00.01
p 5/8 EN

Temp.: TFO 366.01
Att: 01 to D00068

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
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.

Safety Data Sheet

Technozym vWF Antigen ELISA



SDS No. RA00.01
p 6/8 EN

Temp.: TFO 366.01
Art. 01 to D00068

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 of contents in accordance with local, state or national legislation. Dispose of this material and its container to hazardous or special waste collection point. Dispose at suitable refuse site.

13.2 Additional Information

Disposal should be in accordance with local, state or national legislation.

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 Very Not listed

High Concern for Authorisation

REACH: ANNEX XIV list of Not listed

substances subject to authorisation

Safety Data Sheet



Technozym vWF Antigen ELISA

SDS No. RA00.01

p 7/8 EN

Temp.: TFO 366.01
Art. 01 to D00068

REACH: Annex XVII Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles
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 2024-02-28 (replaces RB00E.01_SDB from 2019-03-21)
Date of Revision n.a.

LEGEND

Hazard Pictogram(s)



GHS07: Health Hazard

GHS05: Corrosion,
GHS06: Skull and crossbones
GHS09: Environment

Hazard classification

Acute Tox. 3 : Acute toxicity, Category 3
Acute Tox. 2 : Acute toxicity, Category 2
Skin Corr. 1C : Skin corrosion/irritation, Category 1C
Skin Sens. 1A : Skin sensitization, Category 1A
Eye Dam. 1 : Serious eye damage/irritation, Category 1
Aquatic Acute 1 : Hazardous to the aquatic environment, Acute, Category 1
Aquatic Chronic 1 : Hazardous to the aquatic environment, Chronic, Category 1

Hazard Statement(s)

H301: Toxic if swallowed.
H310: Fatal in contact with skin.
H314: Causes severe skin burns and eye damage.
H315: Causes skin irritation
H317: May cause an allergic skin reaction.
H318: Causes serious eye damage.
H319: Causes serious eye irritation
H330: Fatal if inhaled.
H400: Very toxic to aquatic life.
H410: Very toxic to aquatic life with long lasting effects.
P261: Avoid breathing dust/fume/gas/mist/vapours/spray.
P264: wash hands thoroughly after handling
P272: Contaminated work clothing should not be allowed out of the workplace.
P280: Wear protective gloves/protective clothing/eye protection/face protection.
P302+P352: IF ON SKIN: Wash with plenty of water.
P321: Specific treatment (see Medical Advice on this label).
P333+P313: If skin irritation or rash occurs: Get medical advice/attention.
P362+P364: Take off contaminated clothing and wash it before reuse.

Precautionary Statement(s)

Safety Data Sheet



Technozym vWF Antigen ELISA

SDS No. RA00.01

p 8/8 EN

Temp.: TFO 366.01
Art. 01 to D00068

P501: Dispose of contents in accordance with local, state or national legislation.

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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