

# Safety Data Sheet



SDS No. K700.01  
p 1/7 EN R01

Temp.: TF0604.01  
Alt US to D00068

## TECHNOLEIA D-Dimer Latex Kit

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.	TECHNOLEIA D-Dimer Latex Kit	150 Tests // REF 4847200 // 50 Tests REF 4847210
Product Components	Component 1 TECHNOLEIA D-Dimer Buffer	1 x 21 mL// 1 x 7 mL
	Component 2 TECHNOLEIA D-Dimer Latex	1 x 12 mL// 1 x 4 mL
	Component 3 TECHNOLEIA D-Dimer CAL 0 ng/mL	1 x 1 mL
	Component 4 TECHNOLEIA D-Dimer CAL ~3000 ng/mL	1 x 1 mL
	Component 5 NaCl solution, 0.9%	1 x 8 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

Component 1	TECHNOLEIA D-Dimer Buffer	Regulation (EC) No. 1272/2008 (CLP) Not classified as dangerous for supply/use
Component 2	TECHNOLEIA D-Dimer Latex	Not classified as dangerous for supply/use
Component 3	TECHNOLEIA D-Dimer CAL 0 ng/mL	Not classified as dangerous for supply/use
Component 4	TECHNOLEIA D-Dimer CAL ~3000 ng/mL	Not classified as dangerous for supply/use
Component 5	NaCl solution, 0.9%	Not classified as dangerous for supply/use

#### 2.2 Label elements

Product Name	According to Regulation (EC) No. 1272/2008 (CLP) TECHNOLEIA D-Dimer Latex Kit
Hazard Pictogram(s)	None.

#### 2.3 Other hazards

None known.

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### 2.4 Additional Information

Component 1	TECHNOLEIA D-Dimer Buffer	The usual precautions for handling chemicals should be observed.
Component 2	TECHNOLEIA D-Dimer Latex	The usual precautions for handling chemicals should be observed.
Component 3	TECHNOLEIA D-Dimer CAL 0 ng/mL	Contains human derived material - potentially biohazardous
Component 4	TECHNOLEIA D-Dimer CAL ~3000 ng/mL	Contains human derived material - potentially biohazardous
Component 5	NaCl solution, 0.9%	The usual precautions for handling chemicals should be observed.

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 Substances

Not applicable.

### 3.2 Mixtures

Product does not contain any hazardous ingredients.

## 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.

## 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.

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### 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	TECHNOLEIA D-Dimer Buffer	liquid
Component 2	TECHNOLEIA D-Dimer Latex	liquid
Component 3	TECHNOLEIA D-Dimer CAL 0	solid (lyoph.)
Component 4	TECHNOLEIA D-Dimer CAL ~3000	solid (lyoph.)
Component 5	NaCl solution, 0.9%	liquid

Colour

Component 1	TECHNOLEIA D-Dimer Buffer	without colour
Component 2	TECHNOLEIA D-Dimer Latex	white
Component 3	TECHNOLEIA D-Dimer CAL 0	white-yellowish
Component 4	TECHNOLEIA D-Dimer CAL ~3000	white-yellowish
Component 5	NaCl solution, 0.9%	without colour

Odour – all components odourless  
Melting point/freezing point Not known.  
Boiling point or initial boiling point and boiling range Not applicable.

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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
STOT - single exposure	Not classified
STOT - repeated exposure	Not classified
Aspiration hazard	Not classified

### 11.2 Information on other hazards

Not known.

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### 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.

#### 14.6 Special precautions for user

Not known

#### 14.7 Maritime transport in bulk according to IMO instruments

Not known

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### 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) N° 2019/1021 of Not listed  
the 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) N° 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

A REACH chemical safety assessment has not been carried out.

### SECTION 16: OTHER INFORMATION

Major additions, deletions or changes to previous version are indicated by lines in the margin.

#### LEGEND

Hazard Pictogram(s) 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  
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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