

Section 1. Identification of the substance / mixture and of the company

1.1 Product identifier

D-Dimer test kit, ST 0150 & ST 0151

Reagent R1 – cuvette

Reagent R2 – cap

1.2 Relevant identified uses of the substance or mixture and uses advised against Identified uses

In-vitro diagnostics; please refer to the product insert.

1.3 Supplier's details

Company name	Eurolyser Diagnostica GmbH
Address, P.O. Box	Bindergasse 3
Postcode / Place	5020 Salzburg
Country	Österreich
Telephone	+43 662 432100
Facsimile	+43 662 432100 50
E-Mail	sds@eurolyser.com

1.4 Emergency telephone number

Toxicological information-emergency centre +43 1 406 43 43

MO – SU, 0 – 24 h German and English

Section 2. Hazards Identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 (CLP)

Reagent 1	not classified as hazardous
Reagent 2	not classified as hazardous

2.2 Label elements

Reagent 1	has not to be labelled
Reagent 2	has not to be labelled
Hazard pictograms	not applicable
Signal words	not applicable

Hazard statement(s) in full	not applicable
Precautionary statement(s) in full	not applicable
Any additional hazardous information (EU)	not applicable
Any additional applicable label elements	not applicable

2.3 Other hazards

No data available.

Section 3. Composition / information on ingredients

3.1 Substance

Not applicable.

3.2 Mixture

Reagent 1

The following ingredients are classified as dangerous:

Substance	Identifier	w.%	Classification in acc. with 1272/2008/EC
Trizma Base (Reagent 1 only)	CAS-No. 77-86-1	1.2	Eye Irrit. 2, H319 STOT SE 3, H335 Skin Irrit. 2, H315

For the full text of the H-statements mentioned in this Section, see Section 16.

Section 4. First aid measures

4.1 Description of first aid measures

4.1.1 General notes

Dilutable with water. Remove contaminated clothing.

4.1.2 Following inhalation

Supply fresh air. If you feel unwell, consult a doctor. In case of unconscious place in recovery position.

4.1.3 Following skin contact

Rinse skin with soap and water. If symptoms persist, consult a doctor.

4.1.4 Following eye contact

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

4.1.5 Following ingestion

Give water to drink. Seek medical advice immediately. Induce vomiting.

4.1.6 Self-protection of the first aider

No data available.

4.2 Most important symptoms and effects, both acute and delayed

No additional information available.

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

Section 5. Firefighting measures

5.1 Extinguishing media

5.1.1 Suitable extinguishing media

Water spray. Dry powder. Foam. Carbon dioxide.

5.1.2 Unsuitable extinguishing media

Not applicable.

5.2 Special hazards arising from the substance or mixture

The product is non-reactive under normal conditions of use, storage and transport. Fires in the immediate vicinity may cause the development of dangerous vapours.

5.3 Advice for firefighters

Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

Section 6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Preventive skin protection recommended. Use disposable gloves. Do not swallow.

6.1.1 For non-emergency personnel

Ventilate spillage area.

6.1.2 For emergency responders

Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

6.2 Environmental precautions

Avoid emissions into soil or water. Retain contaminated water and dispose it in accordance to local regulations.

6.3 Methods and materials for containment and cleaning up

6.3.1 Appropriate containment

Cover drains. Collect, bind and pump off spills. Collect the material for disposal in tightly closed containers.

6.3.2 Clean-up procedures

Spillages should be washed with soap and water.

6.3.3 Other information

No further information.

6.4 Reference to other sections

Refer additionally to chapter 7, 8 and 13.

Section 7. Handling and storage

7.1 Precautions for safe handling

Provide adequate ventilation, and local exhaust as needed. Avoid contact with skin, eyes, and clothing. Wear personal protective equipment. Do not eat, drink or smoke when using this product. Do not inhale substance. After worktime and during work intervals the affected skin areas must be thoroughly cleaned.

7.2 Conditions for safe storage, including any incompatibilities

Store according to temperature stated on the product label or according to the package insert provided. Avoid direct sunlight and temperature outside the recommended storage conditions.

7.3 Specific end use(s)

No data available.

Section 8. Exposure controls / personal protection

8.1 Control parameters

No additional information available.

8.2 Exposure controls

8.2.1 Appropriate engineering controls

Handle in accordance with good industrial hygiene and safety practice. Ensure adequate ventilation.

8.2.2 Personal protective equipment

Avoid skin and eye contact. Wash hands before breaks and immediately after product handling. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the workplace.

8.2.2.1 Eye / face protection

Avoid skin and eye contact. Use safety glasses

8.2.2.2 Skin protection

Use appropriate disposal gloves according to EN 374. It is recommended to check the chemical resistance of the protective gloves. Also pay attention to a proper method to strip off the gloves. Wear suitable protective clothing.



8.2.2.3 Respiratory protection

In case of insufficient ventilation, wear suitable respiratory equipment.

8.2.2.4 Thermal hazards

Not relevant.

8.2.3 Environmental exposure controls

Avoid emissions into soil or water.

Section 9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

	<u>Reagent 1</u>	<u>Reagent 2</u>
Appearance		
Physical state	Fluidic solution	Fluidic solution
Color	No data available	No data available
Odour	No data available	No data available
Odour threshold	No data available	No data available

Other physical and chemical parameters

pH-value	No data available	No data available
Melting point / freezing point	Not applicable	Not applicable
Initial boiling point / boiling range	No data available	No data available
Flash point	No data available	No data available
Evaporation rate	No data available	No data available
Flammability (solid, gas)	Not applicable	Not applicable

Flammability or explosive limits

Upper limit	No data available	No data available
Lower limit	No data available	No data available

Vapour pressure	No data available	No data available
Vapour density	No data available	No data available
Relative density	No data available	No data available

Solubility(ies)

Water solubility	No data available	No data available
<u>Partition coefficient</u> n-Octanol/water	No data available	No data available
Auto-ignition temperature	No data available	No data available
Decomposition temperature	No data available	No data available
Viscosity	No data available	No data available
Explosive properties	No data available	No data available
Oxidising properties	No data available	No data available

9.2 Other information

No data available.

Section 10. Stability and Reactivity

10.1 Reactivity

No hazardous reactions for the mixture and the contained substances in dissolved state were observed.

10.2 Chemical stability

Both reagents are stable under normal ambient conditions and at normal storage and handling conditions.

10.3 Possibility of hazardous reactions

No hazardous reactions known.

10.4 Conditions to avoid

Avoid direct sunlight, vibration or high temperature.

10.5 Incompatible materials

No additional information available.

10.6 Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

Section 11. Toxicological information

11.1 Information on toxicological effects

11.1.1 Toxicological effects

Reagent 1 and Reagent 2

Acute toxicity (oral)	No data available
Acute toxicity (dermal)	No data available
Acute toxicity (inhalative)	No data available
Skin corrosion/irritation	No data available
Eye damage/irritation	No data available
Sensitisation to the respiratory tract	No data available
Skin sensitisation	No data available
Germ cell mutagenicity/Genotoxicity	No data available
Carcinogenicity	No data available
Reproductive toxicity	No data available
Effects on or via lactation	No data available
STOT (single exposure)	No data available
STOT (repeated exposure)	No data available
Aspiration hazard	No data available

11.1.2 Other information

No data available.

Section 12. Ecological information

12.1 Toxicity

No data available.

12.2 Persistence and degradability

No data available.

12.3 Bioaccumulative potential

No data available.

12.4 Mobility in soil

No data available.

12.5 Results of PBT and vPvB assessment

No data available.

12.6 Other adverse effects

General information: Do not allow to enter into ground-water, surface water or drains.

12.7 Other information

No data available.

Section 13. Disposal considerations

13.1 Waste treatment methods

13.1.1 Product and packaging disposal

Waste disposal must be in accordance with appropriate Federal and local regulations.

13.1.2 Waste treatment-relevant information

Avoid emissions into soil or water. Retain contaminated water and dispose it in accordance to local regulations. Cover drains. Collect, bind and pump off spills.

13.1.3 Sewage disposal-relevant information

Avoid emissions into soil or water.

13.1.4 Other disposal recommendations

No data available

Section 14. Transport information

14.1 UN number

Transportation of the product is not regulated by ADR.

14.2 UN proper shipping name

Not relevant.

14.3 Transport hazard class(es)

Not relevant.

14.4 Packaging group

Not relevant.

14.5 Environmental hazards

No. (Not dangerous for the environment according to dangerous goods regulation).

14.6 Special precautions for user

No dangerous good in sense of these transport regulations.

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code

No data available.

Section 15. Regulatory information**15.1 Safety, health and environmental regulations / legislation specific for the substance or mixture****Reagent 1 and Reagent 2**

Classification, labelling and packaging of substances and mixtures (CLP)

VO (EG) Nr. 1272/2008

Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

VO (EG) Nr. 2015/830

Regulations of the insurance funds

Federal law on occupational health and safety

BGBl.Nr. 60/2015

15.2 Chemical Safety Assessment

No chemical safety assessment has been carried out for this substance / mixture by the supplier.

Section 16. Other information

Abbreviation

ADR	Accord européen relative au transport international des marchandises Dangereuses par Route
CLP	Classification, Labelling and Packaging
OEL	Occupational Exposure Limit
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
STOT	specific target organ toxicity

Trizma Base

H 315	Causes skin irritation
H 319	Causes serious eye irritation
H 335	May cause respiratory irritation

The information provided in this Safety Data Sheet is provided in the interest of promoting safe handling of the material. While this information is believed to be correct Eurolyser Diagnostica GmbH makes no warranty in respect to any of the information disclosed. Observe all federal, provincial, state and local laws concerning health and pollution.