



# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006 (REACH) and Regulation (EU) No 2020/878

## D-Dimer FS Reagent R2

Material number 1 7268 R2

Revision date: 20.12.2022

Version: 5.1

Replaces version: 5.0

Language: en-DE

Date of print: 11.1.2023

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### SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1 Product identifier

Trade name: D-Dimer FS Reagent R2  
as part of the kits: 1 7268 XX XX XXX  
(The positions X code different packages.)

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

General use: Reagent for in-vitro diagnostics in human samples  
For professional use only.

#### 1.3 Details of the supplier of the safety data sheet

Company name: DiaSys Diagnostic Systems GmbH  
Street/POB-No.: Alte Strasse 9  
Postal Code, city: DE-65558 Holzheim  
WWW: <http://www.diasys.de>  
E-mail: [mail@diasys.de](mailto:mail@diasys.de)  
Telephone: +49 (0) 6432-9146-0  
Telefax: +49 (0) 6432-9146-32  
Department responsible for information:  
Corporate headquarters, Telephone: +49 (0) 6432-9146-0, Email: [mail@diasys.de](mailto:mail@diasys.de)

#### 1.4 Emergency telephone number

Infraserv, Telephone: +49 (0) 69-305-6418

### SECTION 2: Hazards identification

#### 2.1 Classification of the substance or mixture

##### Classification according to EC regulation 1272/2008 (CLP)

This mixture is classified as not hazardous.

#### 2.2 Label elements

##### Labelling (CLP)

Hazard statements: not applicable

Precautionary statements: not applicable

#### 2.3 Other hazards

Contact with skin and eyes, or inhalation may cause irritations.

Endocrine disrupting properties, Results of PBT and vPvB assessment:

No data available

### SECTION 3: Composition/information on ingredients

3.1 Substances: not applicable

#### 3.2 Mixtures

Chemical characterisation: aqueous solution

Additional information: The product does not contain dangerous substances above limits that need to be mentioned in this section according to applicable EU-legislation.

Contains Sodium azide (0,95 g/L) as preservative.

### SECTION 4: First aid measures

#### 4.1 Description of first aid measures

- In case of inhalation: Move victim to fresh air, put at rest and loosen restrictive clothing.  
If the casualty has difficulty breathing, call a doctor immediately.
- Following skin contact: Change contaminated clothing. Remove residues with water.  
In case of skin reactions, consult a physician.
- After eye contact: Immediately flush eyes with plenty of flowing water for 10 to 15 minutes holding eyelids apart. In case of troubles or persistent symptoms, consult an ophthalmologist.
- After swallowing: Rinse mouth thoroughly with water. Induce vomiting.  
Have victim drink large quantities of water, with active charcoal if possible. Seek medical attention.

#### 4.2 Most important symptoms and effects, both acute and delayed

Contact with skin and eyes, or inhalation may cause irritations.

#### 4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

### SECTION 5: Firefighting measures

#### 5.1 Extinguishing media

Suitable extinguishing media: Water spray jet, dry extinguishing powder, foam.

#### 5.2 Special hazards arising from the substance or mixture

Fires in the immediate vicinity may cause the development of dangerous vapours.  
In case of fire may be liberated: Nitrogen oxides (NOx), carbon monoxide and carbon dioxide.

#### 5.3 Advice for firefighters

Special protective equipment for firefighters:

Wear self-contained breathing apparatus.

Additional information:

Do not allow fire water to penetrate into surface or ground water.

### SECTION 6: Accidental release measures

#### 6.1 Personal precautions, protective equipment and emergency procedures

Avoid contact with skin and eyes.

#### 6.2 Environmental precautions

Do not allow to penetrate into soil, waterbodies or drains.

#### 6.3 Methods and material for containment and cleaning up

Soak up with absorbent materials such as sand, siliceous earth, acid- or universal binder. Store in special closed containers and dispose of according to ordinance. Final cleaning.

#### 6.4 Reference to other sections

Refer additionally to section 8 and 13.

### SECTION 7: Handling and storage

#### 7.1 Precautions for safe handling

Advices on safe handling: Avoid contact with skin and eyes. Do not breathe vapours.  
Keep all containers, equipment and working place clean.

### 7.2 Conditions for safe storage, including any incompatibilities

Requirements for storerooms and containers:

Store container tightly closed in a dry and cool place.

Storage temperature 2 - 8 °C.

Qualified materials: polypropylene, polyethylene

Hints on joint storage:

Do not store together with metal salts.

Storage class:

12 = Non-combustible liquids

### 7.3 Specific end use(s)

No information available.

## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

Additional information:

Contains no substances with occupational exposure limit values.

### 8.2 Exposure controls

Provide adequate ventilation, and local exhaust as needed.

### Personal protection equipment

#### Occupational exposure controls

Respiratory protection:

Provide adequate ventilation.

Hand protection:

Protective gloves according to EN 374.

Glove material: Nitrile rubber-Breakthrough time: >480 min.

Observe glove manufacturer's instructions concerning penetrability and breakthrough time.

Eye protection:

Tightly sealed goggles according to EN 166.

Body protection:

Lab coat

General protection and hygiene measures:

Change contaminated clothing.

Wash hands before breaks and after work.

Provide a conveniently located eye rinse station.

### Environmental exposure controls

Refer to "6.2 Environmental precautions".

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

Physical state at 20 °C and 101.3 kPa

liquid

Colour:

milky, white

Odour:

no characteristic odour

Odour threshold:

No data available

Melting point/freezing point:

No data available

Initial boiling point and boiling range:

No data available

Flammability:

No data available

Upper/lower flammability or explosive limits:

No data available

Flash point/flash point range:

not combustible

Decomposition temperature:

No data available

pH:

at 25 °C: 7,50

Viscosity, kinematic:

No data available

Water solubility:

completely miscible

Partition coefficient: n-octanol/water:

No data available

Vapour pressure: No data available  
Density: at 20 °C: 0,9987 g/mL  
Vapour density: No data available  
Particle characteristics: Not applicable

### 9.2 Other information

Explosive properties: No data available  
Oxidizing characteristics: No data available  
Auto-ignition temperature: No data available  
Evaporation rate: No data available  
Additional information: No data available

## SECTION 10: Stability and reactivity

### 10.1 Reactivity

No data available

### 10.2 Chemical stability

Stable under recommended storage conditions.

### 10.3 Possibility of hazardous reactions

No hazardous reaction when handled and stored according to provisions.

### 10.4 Conditions to avoid

Protect against heat /sun rays. Protect from frost.

### 10.5 Incompatible materials

Strong acids and alkalis

### 10.6 Hazardous decomposition products

No decomposition when used properly.  
Thermal decomposition: No data available

## SECTION 11: Toxicological information

### 11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Toxicological effects: Acute toxicity (oral): Lack of data.  
Acute toxicity (dermal): Lack of data.  
Acute toxicity (inhalative): Lack of data.  
Skin corrosion/irritation: Lack of data.  
Serious eye damage/irritation: Lack of data.  
Sensitisation to the respiratory tract: Lack of data.  
Skin sensitisation: Lack of data.  
Germ cell mutagenicity/Genotoxicity: Lack of data.  
Carcinogenicity: Lack of data.  
Reproductive toxicity: Lack of data.  
Effects on or via lactation: Lack of data.  
Specific target organ toxicity (single exposure): Lack of data.  
Specific target organ toxicity (repeated exposure): Lack of data.  
Aspiration hazard: Lack of data.

**11.2 Information on other hazards**

Endocrine disrupting properties: No data available

Other information: Contact with skin and eyes, or inhalation may cause irritations.

Contains Sodium azide (0,95 g/L):

After resorption of toxic quantities: headache, dizziness, nausea, cough, vomiting, spasms, breathing paralysis, CNS disorders, low blood pressure, cardiovascular failure, unconsciousness, collapse.

**SECTION 12: Ecological information****12.1 Toxicity**

Water Hazard Class: 1 = slightly hazardous to water

**12.2 Persistence and degradability**

Further details: No data available

**12.3 Bioaccumulative potential**

Partition coefficient: n-octanol/water:

No data available

**12.4 Mobility in soil**

No data available

**12.5 Results of PBT and vPvB assessment**

No data available

**12.6 Endocrine disrupting properties**

No data available

**12.7 Other adverse effects**

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

**SECTION 13: Disposal considerations****13.1 Waste treatment methods****Product**

Waste key number: 16 05 06\* = Laboratory chemicals, consisting of or containing hazardous substances, including mixtures of laboratory chemicals.

\* = Evidence for disposal must be provided.

Recommendation: Special waste. Dispose of waste according to applicable legislation.

**Package**

Waste key number: 15 01 02 = Plastic packaging

Recommendation: Dispose of waste according to applicable legislation.

Non-contaminated packages may be recycled.

**SECTION 14: Transport information****14.1 UN number or ID number**

ADR/RID, ADN, IMDG, IATA-DGR:

not applicable



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#### 14.2 UN proper shipping name

ADR/RID, ADN, IMDG, IATA-DGR:

Not restricted

#### 14.3 Transport hazard class(es)

ADR/RID, ADN, IMDG, IATA-DGR:

not applicable

#### 14.4 Packing group

ADR/RID, ADN, IMDG, IATA-DGR:

not applicable

#### 14.5 Environmental hazards

Dangerous for the environment: Substance/mixture is not environmentally hazardous according to the criteria of the UN model regulations.

Marine pollutant - IMDG:

no

#### 14.6 Special precautions for user

No dangerous good in sense of these transport regulations.

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

No data available

### SECTION 15: Regulatory information

#### 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

##### National regulations - Germany

Storage class: 12 = Non-combustible liquids

Water Hazard Class: 1 = slightly hazardous to water

Further regulations, limitations and legal requirements:

No data available

##### National regulations - EC member states

Further regulations, limitations and legal requirements:

No data available

#### 15.2 Chemical Safety Assessment

For this mixture a chemical safety assessment is not required.

### SECTION 16: Other information

Reason of change: General revision

Date of first version: 14.2.2008

Department issuing data sheet: see section 1: Department responsible for information



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Abbreviations and acronyms: ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways  
ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road  
AS/NZS: Australian Standards/New Zealand Standards  
CAS: Chemical Abstracts Service  
CFR: Code of Federal Regulations  
CLP: Classification, Labelling and Packaging  
CNS: Central Nervous System  
DMEL: Derived minimal effect level  
DNEL: Derived no-effect level  
EC: European Community  
EN: European Standard  
EQ: Excepted quantities  
EU: European Union  
IATA: International Air Transport Association  
IATA-DGR: International Air Transport Association – Dangerous Goods Regulations  
IBC Code: International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk  
IMDG Code: International Maritime Dangerous Goods Code  
MARPOL: Maritime Pollution: The International Convention for the Prevention of Pollution from Ships  
OSHA: Occupational Safety and Health Administration  
PBT: Persistent, bioaccumulative and toxic  
PNEC: Predicted no-effect concentration  
RID: Regulations Concerning the International Carriage of Dangerous Goods by Rail  
TRGS: Technical Rules for Hazardous Substances  
vPvB: Very persistent and very bioaccumulative

The information in this data sheet has been established to our best knowledge and was up-to-date at time of revision. It does not represent a guarantee for the properties of the product described in terms of the legal warranty regulations.