



D-Dimer Assay

Reagents, Calibrators and Controls

Safety Data Sheet 1111

according to Regulation (EC) No. 453/2010

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Version: B

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

1.1. Product identifier

| | |
|---------------|--|
| Product form | Mixture |
| Product name | D-Dimer Assay |
| | Reagent R1, Reagent R2, Calibrators and Controls |
| Product code | DZ179A |
| | DZ179A-R1, DZ179A-R2, DZ179A-CAL, DZ179A-CON |
| Product group | Blend |

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

1.2.1. Relevant identified uses

No additional information available

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Supplier: Diazyme Laboratories
12889 Gregg Court
92064 Poway
T 858-455-4768

Authorized Representative: MDSS GmbH
Schiffgraben 41
Germany
(+49) 511-6262-8630

1.4. Emergency telephone number

Emergency number Contact your local health authority or poison control center in an emergency. Manufacturer contact number for the US is as follows: (858) 455-4768

SECTION 2 Hazards identification

2.1. Classification of the substance or mixture

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

Not classified (for all components)

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

EUH-statements (**Reagent R1 only**) EUH210 - Safety data sheet available on request

2.3. Other hazards

No additional information available (for all components)

SECTION 3 Composition/information on ingredients

3.1. Substance

Not applicable

3.2. Mixture

| Name | Product identifier | % | Classification according to Regulation (EC) No. 1272/2008 [CLP] |
|-------------|---------------------------------------|--------------------------------|---|
| Trizma Base | (CAS No) 77-86-1 (EC no) 201-064-4 | 1.2 (Reagent R1 only) | Eye Irrit. 2, H319 STOT SE 3, H335 Skin Irrit. 2, H315 |

Full text of H-phrases: see section 16

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SECTION 4 First aid measures

4.1. Description of first aid measures

| | |
|---------------------------------------|--|
| First-aid measures after inhalation | Remove person to fresh air and keep comfortable for breathing. |
| First-aid measures after skin contact | Wash skin with plenty of water. |
| First-aid measures after eye contact | Rinse eyes with water as a precaution. |
| First-aid measures after ingestion | Call a poison center or a doctor if you feel unwell. |

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

| | |
|------------------------------|--|
| Suitable extinguishing media | Water spray. Dry powder. Foam. Carbon dioxide. |
|------------------------------|--|

5.2. Special hazards arising from the substance or mixture

| | |
|--|------------------------------|
| Hazardous decomposition products in case of fire | Toxic fumes may be released. |
|--|------------------------------|

5.3. Advice for firefighters

| | |
|--------------------------------|--|
| Protection during firefighting | 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

6.1.1. For non-emergency personnel

| | |
|----------------------|--------------------------|
| Emergency procedures | Ventilate spillage area. |
|----------------------|--------------------------|

6.1.2. For emergency responders

| | |
|----------------------|---|
| Protective equipment | 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 release to the environment.

6.3. Methods and material for containment and cleaning up

| | |
|-------------------------|---|
| Methods for cleaning up | Take up liquid spill into absorbent material. |
| Other information | Dispose of materials or solid residues at an authorized site. |

6.4. Reference to other sections

For further information refer to section 13.

SECTION 7 Handling and storage

7.1. Precautions for safe handling

| | |
|-------------------------------|---|
| Precautions for safe handling | Ensure good ventilation of the work station. Wear personal protective equipment. |
| Hygiene measures | Do not eat, drink or smoke when using this product. Always wash hands after handling the product. |

7.2. Conditions for safe storage, including any incompatibilities

| | |
|--------------------|--|
| Storage conditions | Store in a well-ventilated place. Keep cool. |
|--------------------|--|

7.3. Specific end use(s)

No additional information available

SECTION 8 Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

| | |
|----------------------------------|--|
| Appropriate engineering controls | Ensure good ventilation of the work station. |
|----------------------------------|--|

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| | |
|---------------------------------|--|
| Hand protection | Protective gloves |
| Eye protection | Safety glasses |
| Skin and body protection | Wear suitable protective clothing |
| Respiratory protection | In case of insufficient ventilation, wear suitable respiratory equipment |
| Environmental exposure controls | Avoid release to the environment. |

SECTION 9 Physical and chemical properties

9.1. Information on basic physical and chemical properties

| | |
|--|-------------------|
| Physical state | Liquid |
| Colour | No data available |
| Odour | No data available |
| Odour threshold | No data available |
| pH | No data available |
| Relative evaporation rate (butylacetate=1) | No data available |
| Melting point | Not applicable |
| Freezing point | No data available |
| Boiling point | No data available |
| Flash point | No data available |
| Auto-ignition temperature | No data available |
| Decomposition temperature | No data available |
| Flammability (solid, gas) | Not applicable |
| Vapour pressure | No data available |
| Relative vapour density at 20 °C | No data available |
| Relative density | No data available |
| Solubility | No data available |
| Log Pow | No data available |
| Viscosity, kinematic | No data available |
| Viscosity, dynamic | No data available |
| Explosive properties | No data available |
| Oxidising properties | No data available |
| Explosive limits | No data available |

9.2. Other information

No additional information available

SECTION 10 Stability and reactivity

10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

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

| | |
|----------------|----------------|
| Acute toxicity | Not classified |
|----------------|----------------|

Trizma Base (77-86-1)

| | |
|---------------|------------------|
| LD50 oral rat | 5900 mg/kg (Rat) |
|---------------|------------------|

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| | |
|--|----------------|
| Skin corrosion/irritation | Not classified |
| Serious eye damage/irritation | Not classified |
| Respiratory or skin sensitisation | Not classified |
| Germ cell mutagenicity | Not classified |
| Carcinogenicity | Not classified |
| Reproductive toxicity | Not classified |
| Specific target organ toxicity (single exposure) | Not classified |
| Specific target organ toxicity (repeated exposure) | Not classified |
| Aspiration hazard | Not classified |

SECTION 12 Ecological information

12.1. Toxicity

Ecology - general The product is not considered harmful to aquatic organisms or to cause long-term adverse effects in the environment.

12.2. Persistence and degradability

Trizma Base (77-86-1)

| | |
|-------------------------------|---|
| Persistence and degradability | Biodegradability in water: no data available. |
|-------------------------------|---|

12.3. Bioaccumulative potential

Trizma Base (77-86-1)

| | |
|---------------------------|----------------------------------|
| Log Pow | -1.56 |
| Bioaccumulative potential | Bioaccumulation: not applicable. |

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

No additional information available

SECTION 13 Disposal considerations

13.1. Waste treatment methods

Waste treatment methods Dispose of contents/container in accordance with licensed collector's sorting instructions.

SECTION 14 Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

14.1. UN number

Not regulated for transport

14.2. UN proper shipping name

| | |
|-----------------------------|----------------|
| Proper Shipping Name (ADR) | Not applicable |
| Proper Shipping Name (IMDG) | Not applicable |
| Proper Shipping Name (IATA) | Not applicable |
| Proper Shipping Name (ADN) | Not applicable |
| Proper Shipping Name (RID) | Not applicable |

14.3. Transport hazard class(es)

ADR

| | |
|----------------------------------|----------------|
| Transport hazard class(es) (ADR) | Not applicable |
|----------------------------------|----------------|

IMDG

| | |
|-----------------------------------|----------------|
| Transport hazard class(es) (IMDG) | Not applicable |
|-----------------------------------|----------------|

IATA

| | |
|-----------------------------------|----------------|
| Transport hazard class(es) (IATA) | Not applicable |
|-----------------------------------|----------------|

ADN

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| | |
|----------------------------------|----------------|
| Transport hazard class(es) (ADN) | Not applicable |
|----------------------------------|----------------|

RID

| | |
|----------------------------------|----------------|
| Transport hazard class(es) (RID) | Not applicable |
|----------------------------------|----------------|

14.4. Packing group

| | |
|----------------------|----------------|
| Packing group (ADR) | Not applicable |
| Packing group (IMDG) | Not applicable |
| Packing group (IATA) | Not applicable |
| Packing group (ADN) | Not applicable |
| Packing group (RID) | Not applicable |

14.5. Environmental hazards

| | |
|-------------------------------|--|
| Dangerous for the environment | No |
| Marine pollutant | No |
| Other information | No supplementary information available |

14.6. Special precautions for user

- Overland transport

No data available

- Transport by sea

No data available

- Air transport

No data available

- Inland waterway transport

| | |
|---------------------------|----|
| Carriage prohibited (ADN) | No |
| Not subject to ADN | No |

- Rail transport

| | |
|---------------------------|----|
| Carriage prohibited (RID) | No |
|---------------------------|----|

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable

SECTION 15 Regulatory information

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

15.1.1. EU-Regulations

Contains no substances with Annex XVII restrictions
 Contains no substance on the REACH candidate list
 Contains no REACH Annex XIV substances

15.1.2. National regulations

Germany

| | |
|--|---|
| VwVwS Annex reference | Water hazard class (WGK) 2, hazard to waters (Classification according to VwVwS, Annex 4) |
| 12th Ordinance Implementing the Federal Immission Control Act - 12.BImSchV | Is not subject of the 12. BImSchV (Hazardous Incident Ordinance) |

Netherlands

| | |
|---|-----------------------------------|
| SZW-lijst van kankerverwekkende stoffen | None of the components are listed |
| SZW-lijst van mutagene stoffen | None of the components are listed |
| NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Borstvoeding | None of the components are listed |
| NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Vruchtbaarheid | None of the components are listed |
| NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Ontwikkeling | None of the components are listed |

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15.2. Chemical safety assessment

No additional information available

SECTION 16 Other information

Full text of H- and EUH-statements

| | |
|---------------|--|
| Eye Irrit. 2 | Serious eye damage/eye irritation, Category 2 |
| Skin Irrit. 2 | Skin corrosion/irritation, Category 2 |
| STOT SE 3 | Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation |
| H315 | Causes skin irritation |
| H319 | Causes serious eye irritation |
| H335 | May cause respiratory irritation |
| EUH210 | Safety data sheet available on request |

SDS EU Diazyme with CLP

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product