

D-Dimer Assay Reagents, Calibrators and Controls Safety Data Sheet 1064

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Date of issue: 06/03/2015 Date of Revision: 06/04/2015 Revision: C

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

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

1.3. Details of the supplier of the safety data sheet

Supplier: Diazyme Laboratories 12889 Gregg Court Poway, CA 92064 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 (GHS-US)

Not classified (for all components)

2.2. Label elements

GHS-US labeling

No labeling applicable (for all components)

2.3. Other hazards

No additional information available (for all components)

2.4. Unknown acute toxicity (GHS-US)

Not applicable (for all components)

SECTION 3 Composition/information on ingredients

3.1. Substance

Not applicable

3.2. Mixture

Name	Product identifier	%	Classification (GHS-US)
Trizma Base	(CAS No) 77-86-1	1.2 (Reagent	Skin Irrit. 2, H315
		R1 only)	STOT SE 3, H335

Full text of H-phrases: see section 16

SECTION 4 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/doctor/physician if you feel unwell.

06/03/2015 SDS 1064 Rev C EN (English US) Page 1

Reagents, Calibrators and Controls

Safety Data Sheet 1064

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

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

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

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

D-Dimer Assay Reagents, Calibrators and Controls		
ACGIH	Not applicable	
OSHA	Not applicable	
Trizma Base (77-86-1)		
ACGIH	Not applicable	
OSHA	Not applicable	

8.2. Exposure controls

Appropriate engineering controls	Ensure good ventilation of the work station.
Appropriate engineering controls	Ensure good ventuation of the work station.

Hand protection Protective gloves.

Eye protection Safety glasses.

06/03/2015 SDS 1064 Rev C EN (English US) 2/1

Reagents, Calibrators and Controls

Safety Data Sheet 1064

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

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

Color Mixture contains one or more component(s) which have the following colour(s):

Colourless to white White to light yellow

Odor There may be no odour warning properties, odour is subjective and inadequate to warn of overexposure.

Mixture contains one or more component(s) which have the following odour(s):

Mild odour Amine-like odour Odourless Sweet odour

Odor threshold No data available pН No data available Not applicable Melting point Freezing point No data available Boiling point No data available No data available Flash point Relative evaporation rate (butyl acetate=1) No data available No data available Flammability (solid, gas) No data available Explosion limits Explosive properties No data available No data available Oxidizing properties Vapor pressure No data available No data available Relative density No data available Relative vapor density at 20 °C

Solubility Water Solubility in water of component(s) of the mixture:

• : > 10 g/100 ml • : > 55 g/100 ml

Log PowNo data availableLog KowNo data availableAuto-ignition temperatureNo data availableDecomposition temperatureNo data availableViscosityNo data availableViscosity, kinematicNo data availableViscosity, dynamicNo 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.

06/03/2015 SDS 1064 Rev C EN (English US) 3/1

Reagents, Calibrators and Controls

Safety Data Sheet 1064

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

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)
ATE US (oral)	5900.000 mg/kg body weight
Skin corrosion/irritation	Not classified
Serious eye damage/irritation	Not classified
Respiratory or skin sensitization	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

ivironment.

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. Other adverse effects

Effect on the global warming No known ecological damage caused by this product.

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

Department of Transportation (DOT)

In accordance with DOT

Not regulated for transport

Additional information

Other information No supplementary information available.

ADR

No additional information available

06/03/2015 SDS 1064 Rev C EN (English US) 4/1

Reagents, Calibrators and Controls

Safety Data Sheet 1064

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Transport by sea

No additional information available

Air transport

No additional information available

SECTION 15 Regulatory information

15.1. US Federal regulations

Trizma Base (77-86-1)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

15.2. International regulations

CANADA

No additional information available

EU-Regulations

No additional information available

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

Not classified

Classification according to Directive 67/548/EEC [DSD] or 1999/45/EC [DPD]

No additional information available

National regulations

No additional information available

15.3. US State regulations

No additional information available

SECTION 16 Other information

Full text of H-phrases

Skin Irrit. 2	Skin corrosion/irritation Category 2
STOT SE 3	Specific target organ toxicity (single exposure) Category 3
H315	Causes skin irritation
H335	May cause respiratory irritation

SDS US Diazyme

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

06/03/2015 SDS 1064 Rev C EN (English US) 5/1