



Diazyme Lp(a) Assay- B Version Reagents, Calibrator, and Control Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Issue Date: 2018/05/16

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Revision: 2

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

1.1. Product identifier

Product form	Mixture
Product name	Diazyme Lp(a) Assay - B Version Reagent R1, Reagent R2, Calibrator, and Control
Product code	DZ131B DZ131B-R1, DZ131B-R2, DZ131B-CAL, DZ131B-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

2.2. Label elements

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

EUH phrases EUH210 - Safety data sheet available on request.

2.3. Other hazards

Adverse physicochemical, human health and environmental effects To our knowledge, this product does not present any particular risk, provided it is handled in accordance with good occupational hygiene and safety practice.

SECTION 3 Composition/Information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Trizma Base	(CAS-No.) 77-86-1 (EC-No.) 201-064-4	1.21 (Reagent R1 only)	Eye Irrit. 2, H319 STOT SE 3, H335 Skin Irrit. 2, H315

Full text of H- and EUH-statements: 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/doctor/physician 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.
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5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire	Toxic fumes may be released.
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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.
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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.
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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".
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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.
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7.3. Specific end use(s)

No additional information available

SECTION 8 Exposure controls/personal protection

8.1. Control parameters

No additional information available

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8.2. Exposure controls

Appropriate engineering controls	Standard safety precautions
Hand protection	Protective gloves
Eye protection	Safety glasses
Skin and body protection	Wear suitable protective clothing
Respiratory protection	Standard safety precautions



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	No data available
Odor	No data available
Odor threshold	No data available
pH	No data available
Relative evaporation rate (butyl acetate=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
Vapor pressure	No data available
Relative vapor density at 20°C	No data available
Relative density	No data available
Solubility	No data available
Partition coefficient n-octanol/water (Log Pow)	No data available
Viscosity, kinematic	No data available
Viscosity, dynamic	No data available
Explosive properties	No data available
Oxidizing properties	No data available
Explosion 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.

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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)

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

STOT-single exposure Not classified

STOT-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)	
Partition coefficient n-octanol/water (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

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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
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IMDG

Transport hazard class(es) (IMDG)	Not applicable
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IATA

Transport hazard class(es) (IATA)	Not applicable
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ADN

Transport hazard class(es) (ADN)	Not applicable
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RID

Transport hazard class(es) (RID)	Not applicable
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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
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14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable

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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 REACH substances with Annex XVII restrictions

Contains no REACH candidate substance

Contains no REACH Annex XIV substances.

15.1.2. National regulations

Germany

VwVwS Annex reference

Water hazard class (WGK) 1, low 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

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16 Other information

Full text of H- and EUH-phrases

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.