

according to Regulation (EC) No. 453/2010

Date of issue: 03/06/2015 Revision date: 04/06/2015 Version: B

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

1.1. Product identifier

Product form Mixture

Product name Direct Enzymatic HbA1c Calibrators, Controls and Blank Solution

Product code DZ168A-CAL, DZ168A-CON, DZ168A-S0V

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

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

EUH-statements EUH210 - Safety data sheet available on request

2.3. Other hazards

No additional information available

SECTION 3 Composition/information on ingredients

3.1. Substance

Not applicable

3.2. Mixture

This mixture does not contain any substances to be mentioned according to the criteria of section 3.2 of REACH annex II

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.

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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

Hand protection Protective gloves
Eye protection Safety glasses

Skin and body protection Wear suitable protective clothing

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

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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 Skin corrosion/irritation Not classified Not classified Serious eye damage/irritation 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

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SECTION 12 Ecological information

Toxicity 12.1.

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

environment.

Persistence and degradability

No additional information available

Bioaccumulative potential

No additional information available

Mobility in soil

No additional information available

Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

No additional information available

SECTION 13 Disposal considerations

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

UN number 14.1.

UN-No. (ADR) Not applicable 1897 UN-No. (IMDG) UN-No. (IATA) 1897 UN-No. (ADN) Not applicable Not applicable

UN-No. (RID)

UN proper shipping name

Proper Shipping Name (ADR) Not applicable

Proper Shipping Name (IMDG) TETRACHLOROETHYLENE

Proper Shipping Name (IATA) Tetrachloroethylene Proper Shipping Name (ADN) Not applicable Proper Shipping Name (RID) Not applicable

Transport document description (IMDG) UN 1897 TETRACHLOROETHYLENE, 6.1, III, MARINE POLLUTANT

Transport hazard class(es) 14.3.

ADR

Transport hazard class(es) (ADR) Not applicable

Transport hazard class(es) (IMDG) 6.1 Danger labels (IMDG) 6.1



IATA

Transport hazard class(es) (IATA) 6.1 Hazard labels (IATA) 6.1

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ADN

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) III
Packing group (IATA) III

Packing group (ADN) Not applicable
Packing group (RID) Not applicable

14.5. Environmental hazards

Dangerous for the environment No

Marine pollutant Yes (IMDG only)

Other information No supplementary information available

14.6. Special precautions for user

- Overland transport

No data available

- Transport by sea

Limited quantities (IMDG) 5 L
Excepted quantities (IMDG) E1

Packing instructions (IMDG) P001, LP01
IBC packing instructions (IMDG) IBC03
Tank instructions (IMDG) T4
Tank special provisions (IMDG) TP1
EmS-No. (Fire) F-A
EmS-No. (Spillage) S-A
Stowage category (IMDG) A

- Air transport

PCA Excepted quantities (IATA) E1 PCA Limited quantities (IATA) Y642 PCA limited quantity max net quantity (IATA) 2LPCA packing instructions (IATA) 655 60L PCA max net quantity (IATA) CAO packing instructions (IATA) 663 CAO max net quantity (IATA) 220L ERG code (IATA) 6L

- 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

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SECTION 15 Regulatory information

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

Water hazard class (WGK) 1, low hazard to waters (Classification according to VwVwS, Annex 4) VwVwS Annex reference Is not subject of the 12. BlmSchV (Hazardous Incident Ordinance)

12th Ordinance Implementing the Federal Immission

Control Act - 12.BImSchV

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 None of the components are listed

giftige stoffen – Borstvoeding

NIET-limitatieve lijst van voor de voortplanting

giftige stoffen - Vruchtbaarheid

NIET-limitatieve lijst van voor de voortplanting

giftige stoffen - Ontwikkeling

None of the components are listed

None of the components are listed

Chemical safety assessment

No additional information available

SECTION 16 Other information

Full text of H- and EUH-statements

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

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