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

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.
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

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.
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
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according to Regulation (EC) No. 453/2010

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

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

No additional information available

12.3. Bioaccumulative potential

No additional information available

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

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

14.2. 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

14.3. Transport hazard class(es)

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

IMDG
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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according to Regulation (EC) No. 453/2010

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) 2L
PCA packing instructions (IATA) 655
PCA max net quantity (IATA) 60L
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
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 12th Ordinance Implementing the Federal Immission Control Act - 12.BImSchV
Water hazard class (WGK) 1, low hazard to waters (Classification according to VwVwS, Annex 4)
Is not subject of the 12. BlmSchV (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 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.