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

1.1. Product form
Mixture

1.1. Product name
Direct Enzymatic HbA1c
Reagent R1A, Reagent R1B, Reagent R2 and Lysis Buffer

1.1. Product code
DZ168A
DZ168A-R1A, DZ168A-R1B, DZ168A-R2, DZ168A-L

1.1. 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
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]
No labelling applicable

2.3. Other hazards
Contains PBT/vPvB substances >= 0.1% assessed in accordance with REACH Annex XIII

SECTION 3 Composition/information on ingredients

3.1. Substance
Not applicable

3.2. Mixture

<table>
<thead>
<tr>
<th>Name</th>
<th>Product identifier</th>
<th>%</th>
<th>Classification according to Regulation (EC) No. 1272/2008 [CLP]</th>
</tr>
</thead>
<tbody>
<tr>
<td>CHES</td>
<td>(CAS No) 103-47-9</td>
<td>2</td>
<td>Eye Irrit. 2, H319</td>
</tr>
<tr>
<td></td>
<td>(EC no) 203-115-6</td>
<td></td>
<td>STOT SE 3, H335</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Skin Irrit. 2, H315</td>
</tr>
</tbody>
</table>
Direct Enzymatic HbA1c
Reagents and Lysis Buffer
Safety Data Sheet 1107

according to Regulation (EC) No. 453/2010

<table>
<thead>
<tr>
<th>Triton X-100</th>
<th>(CAS No) 9002-93-1</th>
<th>0.5 (R1A and R2 only)</th>
<th>Acute Tox. 4 (Oral), H302 Eye Dam. 1, H318</th>
</tr>
</thead>
<tbody>
<tr>
<td>substance listed as REACH Candidate (4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated (covering well-defined substances and UNCB substances, polymers and homologues)) non-classified PBT substance non-classified vPvB substance</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Full text of H-phrases: see section 16

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

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

<table>
<thead>
<tr>
<th>Safety Measure</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appropriate engineering controls</td>
<td>Ensure good ventilation of the work station.</td>
</tr>
<tr>
<td>Hand protection</td>
<td>Protective gloves</td>
</tr>
<tr>
<td>Eye protection</td>
<td>Safety glasses</td>
</tr>
<tr>
<td>Skin and body protection</td>
<td>Wear suitable protective clothing</td>
</tr>
<tr>
<td>Respiratory protection</td>
<td>In case of insufficient ventilation, wear suitable respiratory equipment</td>
</tr>
<tr>
<td>Environmental exposure controls</td>
<td>Avoid release to the environment.</td>
</tr>
</tbody>
</table>

### SECTION 9 Physical and chemical properties

#### 9.1. Information on basic physical and chemical properties

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

#### 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

<table>
<thead>
<tr>
<th>Toxicity</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute toxicity</td>
<td>Not classified</td>
</tr>
</tbody>
</table>

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Direct Enzymatic HbA1c
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Safety Data Sheet 1107

according to Regulation (EC) No. 453/2010

### Triton X-100 (9002-93-1)

<table>
<thead>
<tr>
<th>Parameter Description</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>LD50 oral rat</td>
<td>1800 mg/kg (Rat)</td>
</tr>
<tr>
<td>LD50 dermal rabbit</td>
<td>&gt; 3000 mg/kg (Rabbit)</td>
</tr>
</tbody>
</table>

- 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.

<table>
<thead>
<tr>
<th>Parameter Description</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>LC50 fish 1</td>
<td>&gt; 10 mg/l (96 h; Lepomis macrochirus; Toxicity test)</td>
</tr>
<tr>
<td>EC50 Daphnia 1</td>
<td>26 mg/l (48 h; Daphnia magna)</td>
</tr>
<tr>
<td>EC50 other aquatic organisms 1</td>
<td>10 mg/l (336 h; Lemna sp.; Biomass)</td>
</tr>
<tr>
<td>LC50 fish 2</td>
<td>8.9 mg/l (96 h; Pimephales promelas)</td>
</tr>
<tr>
<td>Threshold limit algae 1</td>
<td>500 mg/l (504 h; Selenastrum capricornutum; Cell numbers)</td>
</tr>
</tbody>
</table>

#### 12.2. Persistence and degradability

**CHES (103-47-9)**

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

**Triton X-100 (9002-93-1)**

- Persistence and degradability: Biodegradable in water.
- ThOD: 2.16 g O₂ / g substance

#### 12.3. Bioaccumulative potential

**CHES (103-47-9)**

- Bioaccumulative potential: No bioaccumulation data available.

**Triton X-100 (9002-93-1)**

- Log Pow: 4.86 (Estimated value)

#### 12.4. Mobility in soil

No additional information available

#### 12.5. Results of PBT and vPvB assessment

<table>
<thead>
<tr>
<th>Component</th>
<th>Criteria Met</th>
</tr>
</thead>
<tbody>
<tr>
<td>Triton X-100 (9002-93-1)</td>
<td>This substance/mixture meets the PBT criteria of REACH regulation, annex XIII</td>
</tr>
<tr>
<td></td>
<td>This substance/mixture meets the vPvB criteria of REACH regulation, annex XIII</td>
</tr>
</tbody>
</table>

#### 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
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| 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**
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 a substance on the REACH candidate list in concentration ≥ 0.1% or with a lower specific limit: 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated [covering well-defined substances and UVCB substances, polymers and homologues] (CAS 9002-93-1)
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.BlmSchV**
  - Is not subject of the 12. BlmSchV (Hazardous Incident Ordinance)

**Netherlands**
- **SZW-list van kankerverwekkende stoffen**
  - None of the components are listed
- **SZW-list 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

<table>
<thead>
<tr>
<th>Acute Tox. 4 (Oral)</th>
<th>Acute toxicity (oral), Category 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eye Dam. 1</td>
<td>Serious eye damage/eye irritation, Category 1</td>
</tr>
<tr>
<td>Eye Irrit. 2</td>
<td>Serious eye damage/eye irritation, Category 2</td>
</tr>
<tr>
<td>Skin Irrit. 2</td>
<td>Skin corrosion/irritation, Category 2</td>
</tr>
<tr>
<td>STOT SE 3</td>
<td>Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation</td>
</tr>
<tr>
<td>H302</td>
<td>Harmful if swallowed</td>
</tr>
<tr>
<td>H315</td>
<td>Causes skin irritation</td>
</tr>
<tr>
<td>H318</td>
<td>Causes serious eye damage</td>
</tr>
<tr>
<td>H319</td>
<td>Causes serious eye irritation</td>
</tr>
<tr>
<td>H335</td>
<td>May cause respiratory irritation</td>
</tr>
</tbody>
</table>

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.