

# Safety data sheet

according to 1907/2006/EC, Article 31



Printing date 11.12.2015

Version number 3

Revision: 11.12.2015

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

### 1.1 Product identifier

Trade name: **Enzytec™ Glucose Remover Control solution**

Article number: E3400E00

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

No further relevant information available.

Application of the substance / the preparation: In vitro

### 1.3 Details of the supplier of the safety data sheet

Manufacturer/Supplier:

R-Biopharm AG

An der neuen Bergstraße 17

D-64297 Darmstadt

Further information obtainable from: FE e-mail: info@r-biopharm.de

1.4 Emergency telephone number: FE 0049-6151-8102-0

## SECTION 2: Hazards identification

### 2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008

The product is not classified according to the CLP regulation.

Classification according to Directive 67/548/EEC or Directive 1999/45/EC Not applicable.

Information concerning particular hazards for human and environment:

The product does not have to be labelled due to the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest valid version.

Classification system:

The classification is according to the latest editions of the EU-lists, and extended by company and literature data.

### 2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008 Void

Hazard pictograms Void

Signal word Void

Hazard statements Void

### 2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

## SECTION 3: Composition/information on ingredients

### 3.2 Chemical characterisation: Mixtures

Description: Mixture of substances with nonhazardous additions.

Dangerous components: Void

Additional information: For the wording of the listed hazard phrases refer to section 16.

## SECTION 4: First aid measures

### 4.1 Description of first aid measures

General information: No special measures required.

After inhalation: Supply fresh air; consult doctor in case of complaints.

After skin contact: Immediately wash with water and soap and rinse thoroughly.

After eye contact: Rinse opened eye for several minutes under running water.

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**After swallowing:** If symptoms persist consult doctor.**4.2 Most important symptoms and effects, both acute and delayed**

No further relevant information available.

**4.3 Indication of any immediate medical attention and special treatment needed**

No further relevant information available.

**SECTION 5: Firefighting measures****5.1 Extinguishing media****Suitable extinguishing agents:**CO<sub>2</sub>, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.**5.2 Special hazards arising from the substance or mixture**

No further relevant information available.

**5.3 Advice for firefighters****Protective equipment:** No special measures required.**SECTION 6: Accidental release measures****6.1 Personal precautions, protective equipment and emergency procedures**

Wear protective clothing.

**6.2 Environmental precautions:** No special measures required.**6.3 Methods and material for containment and cleaning up:** Pick up mechanically.**6.4 Reference to other sections**

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

**SECTION 7: Handling and storage****7.1 Precautions for safe handling** No special measures required.**Information about fire - and explosion protection:** No special measures required.**7.2 Conditions for safe storage, including any incompatibilities****Storage:****Requirements to be met by storerooms and receptacles:** No special requirements.**Information about storage in one common storage facility:** Not required.**Further information about storage conditions:** None.**7.3 Specific end use(s)** No further relevant information available.**SECTION 8: Exposure controls/personal protection****Additional information about design of technical facilities:** No further data; see item 7.**8.1 Control parameters****Ingredients with limit values that require monitoring at the workplace:**

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

**Additional information:** The lists valid during the making were used as basis.**8.2 Exposure controls****Personal protective equipment:****General protective and hygienic measures:**

The usual precautionary measures are to be adhered to when handling chemicals.

**Respiratory protection:** Not required.

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**Protection of hands:**

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

**Material of gloves**

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

**Penetration time of glove material**

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

**For the permanent contact gloves made of the following materials are suitable:**

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

**As protection from splashes gloves made of the following materials are suitable:**

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

**Eye protection:** Safety glasses

### SECTION 9: Physical and chemical properties

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

**General Information****Appearance:**

<b>Form:</b>	Solid
<b>Colour:</b>	White
<b>Odour:</b>	Characteristic
<b>Odour threshold:</b>	Not determined.

<b>pH-value:</b>	Not applicable.
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**Change in condition**

<b>Melting point/Melting range:</b>	0 °C
<b>Boiling point/Boiling range:</b>	Undetermined.

<b>Flash point:</b>	Not applicable.
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<b>Flammability (solid, gaseous):</b>	Not determined.
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**Ignition temperature:**

<b>Decomposition temperature:</b>	Not determined.
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<b>Self-igniting:</b>	Product is not selfigniting.
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<b>Danger of explosion:</b>	Product does not present an explosion hazard.
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**Explosion limits:**

<b>Lower:</b>	Not determined.
<b>Upper:</b>	Not determined.

<b>Vapour pressure at 20 °C:</b>	23 hPa
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<b>Density:</b>	Not determined.
<b>Relative density</b>	Not determined.
<b>Vapour density</b>	Not applicable.

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<b>Evaporation rate</b>	Not applicable.
<b>Solubility in / Miscibility with water:</b>	Soluble.
<b>Partition coefficient (n-octanol/water):</b>	Not determined.
<b>Viscosity:</b>	
<b>Dynamic:</b>	Not applicable.
<b>Kinematic:</b>	Not applicable.
<b>Solvent content:</b>	
<b>Organic solvents:</b>	0.0 %
<b>Water:</b>	97.3 %
<b>Solids content:</b>	100.0 %
<b>9.2 Other information</b>	No further relevant information available.

### SECTION 10: Stability and reactivity

**10.1 Reactivity** No further relevant information available.

**10.2 Chemical stability**
**Thermal decomposition / conditions to be avoided:**

No decomposition if used according to specifications.

**10.3 Possibility of hazardous reactions** No dangerous reactions known.

**10.4 Conditions to avoid** No further relevant information available.

**10.5 Incompatible materials:** No further relevant information available.

**10.6 Hazardous decomposition products:** No dangerous decomposition products known.

### SECTION 11: Toxicological information

**11.1 Information on toxicological effects**
**Acute toxicity** Based on available data, the classification criteria are not met.

**LD/LC50 values relevant for classification:**
**50-99-7 glucose**

Oral LD50 25800 mg/kg (rat)

**Primary irritant effect:**
**Skin corrosion/irritation** Based on available data, the classification criteria are not met.

**Serious eye damage/irritation** Based on available data, the classification criteria are not met.

**Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.

**CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
**Germ cell mutagenicity** Based on available data, the classification criteria are not met.

**Carcinogenicity** Based on available data, the classification criteria are not met.

**Reproductive toxicity** Based on available data, the classification criteria are not met.

**STOT-single exposure** Based on available data, the classification criteria are not met.

**STOT-repeated exposure** Based on available data, the classification criteria are not met.

**Aspiration hazard** Based on available data, the classification criteria are not met.

### SECTION 12: Ecological information

**12.1 Toxicity**
**Aquatic toxicity:** No further relevant information available.

**12.2 Persistence and degradability** No further relevant information available.

**12.3 Bioaccumulative potential** No further relevant information available.

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**12.4 Mobility in soil** No further relevant information available.

**Additional ecological information:**
**General notes:** Generally not hazardous for water

**12.5 Results of PBT and vPvB assessment**
**PBT:** Not applicable.

**vPvB:** Not applicable.

**12.6 Other adverse effects** No further relevant information available.

### SECTION 13: Disposal considerations

**13.1 Waste treatment methods**
**Recommendation** Disposal must be made according to official regulations.

**Uncleaned packaging:**
**Recommendation:** Disposal must be made according to official regulations.

**Recommended cleansing agents:** Water, if necessary together with cleansing agents.

### SECTION 14: Transport information

**14.1 UN-Number**

ADR, ADN, IMDG, IATA

Void

**14.2 UN proper shipping name**

ADR, ADN, IMDG, IATA

Void

**14.3 Transport hazard class(es)**

ADR, ADN, IMDG, IATA

Class

Void

**14.4 Packing group**

ADR, IMDG, IATA

Void

**14.5 Environmental hazards:**
**Marine pollutant:**

No

**14.6 Special precautions for user**

Not applicable.

**14.7 Transport in bulk according to Annex II of Marpol and the IBC Code**

Not applicable.

**Transport/Additional information:**

Not dangerous according to the above specifications.

**UN "Model Regulation":**

Void

### SECTION 15: Regulatory information

**15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
**Directive 2012/18/EU**
**Named dangerous substances - ANNEX I** None of the ingredients is listed.

**National regulations:**
**Waterhazard class:** Generally not hazardous for water.

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**15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.**SECTION 16: Other information**

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

**Department issuing MSDS:** QS 0049-6151-8102-0**Contact:** QS 0049-6151-8102-0**Abbreviations and acronyms:**

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

\* **Data compared to the previous version altered.**

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