



## Safety data sheet

According to 1907/2006/EC (REACH), 453/2010/EU, 2015/830/EU

### BIOLABO SAS - HbA1c ENZYM Standard Set - REF22052 R1 1x0.5mL R2 1x0.5mL FDS 22052

#### SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

- 1.1 Product identifier:** BIOLABO SAS - HbA1c ENZYM Standard Set - REF22052 R1 1x0.5mL R2 1x0.5mL  
FDS 22052
- 1.2 Relevant identified uses of the substance or mixture and uses advised against:**  
Relevant uses: In vitro diagnostic. For professional use only.  
Uses advised against: All uses not specified in this section or in section 7.3
- 1.3 Details of the supplier of the safety data sheet:** BIOLABO SAS  
Les Hautes Rives  
02160 Maizy - France  
Phone.: 0323251550 -  
Fax: 0323256256  
info@biolabo.fr  
www.biolabo.fr
- 1.4 Emergency telephone number:** BIOLABO (33) (0) 323251550 ( 08h00-18h00), ORFILA (33)  
(0)145 42 59 59

#### SECTION 2: HAZARDS IDENTIFICATION

- 2.1 Classification of the substance or mixture:**  
**Directive 67/548/EC and Directive 1999/45/EC:**  
In accordance with Directive 67/548/EC and Directive 1999/45/EC, the product is not classified as dangerous.  
**CLP Regulation (EC) n° 1272/2008:**  
The product is not classified as dangerous according to CLP Regulation (EC) n° 1272/2008.
- 2.2 Label elements:**  
**Directive 67/548/EC and Directive 1999/45/EC:**  
In accordance with the legislation, the elements on the label are as follows:  
Not classified as dangerous. Safety data sheet available to professional users that request it.  
**CLP Regulation (EC) n° 1272/2008:**  
**Hazard statements:**  
Non-applicable  
**Precautionary statements:**  
Non-applicable  
**Supplementary information:**  
EUH210: Safety data sheet available on request  
Whole blood : 99%-100% (substance non classée)  
Tetrachloroethylene : < 0.1%, CAS:127-18/4, EINECS:204-825-9  
Classification DPD :Carc . R40, N : R51/53  
Classification CLP : Aquatic Chronic2 : H411 ; Carc. 2 : H351
- 2.3 Other hazards:**  
Each blood donor unit used in the preparation of this product has been tested by an FDA approved method and found non-reactive for the presence of HbsAg, HCV and antibody to HIV 1/2. Because no known test method can offer complete assurance that infectious agents are absent, all human-based products should be handled in accordance with good laboratory practices using appropriate precautions.

#### SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

- 3.1 Substance:**  
Non-applicable
- 3.2 Mixture:**  
**Chemical description:** Mixture composed of organic substances  
**Components:**  
None of the substances contained in the mixture are above the values fixed in Annex II of Regulation (EC) n°1907/2006

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#### SECTION 4: FIRST AID MEASURES

##### 4.1 Description of first aid measures:

Consult a doctor in case of discomfort with this Safety data Sheet.

##### By inhalation:

In case of symptoms, move the person affected into fresh air.

##### By skin contact:

In case of contact it is recommended to clean the affected area thoroughly with water and neutral soap. In case of modifications on the skin (stinging, redness, rashes, blisters,...), seek medical advice with this Safety data Sheet

##### By eye contact:

Rinse with water until the product has been eliminated. In case of problems, consult a doctor with the SDS of this product.

##### By ingestion/aspiration:

In case of consumption in large quantities, it is recommended to seek medical assistance.

##### 4.2 Most important symptoms and effects, both acute and delayed:

Acute and delayed effects are indicated in sections 2 and 11.

##### 4.3 Indication of any immediate medical attention and special treatment needed:

Non-applicable

#### SECTION 5: FIREFIGHTING MEASURES

##### 5.1 Extinguishing media:

Product is non-flammable, low risk of fire by the inflammability characteristics of the product in normal conditions of storage, manipulation and use. In the case of the existence of sustained combustion as a result of improper manipulation, storage or use any type of extinguishing agent can be used (ABC Powder, water,...)

##### 5.2 Special hazards arising from the substance or mixture:

Due to its non-flammable nature, the product does not present a fire risk under normal conditions of storage, manipulation and use.

##### 5.3 Advice for firefighters:

Depending on the magnitude of the fire it may be necessary to use full protective clothing and individual respiratory equipment. Minimum emergency facilities and equipment should be available (fire blankets, portable first aid kit,...) in accordance with Directive 89/654/EC.

##### Additional provisions:

Act in accordance with the Internal Emergency Plan and the Information Sheets on actions to take after an accident or other emergencies. Destroy any source of ignition. In case of fire, refrigerate the storage containers and tanks for products susceptible to inflammation, explosion or BLEVE as a result of high temperatures. Avoid spillage of the products used to extinguish the fire into an aqueous medium.

#### SECTION 6: ACCIDENTAL RELEASE MEASURES

##### 6.1 Personal precautions, protective equipment and emergency procedures:

Sweep up and shovel product or other means and place in container for reuse (preferred) or disposal

##### 6.2 Environmental precautions:

This product is not classified as hazardous to the environment. Keep product away from drains, surface and underground water.

##### 6.3 Methods and material for containment and cleaning up:

It is recommended:

Sweep up and shovel product or other means and place in container for reuse (preferred) or disposal

##### 6.4 Reference to other sections:

See sections 8 and 13.

#### SECTION 7: HANDLING AND STORAGE

##### 7.1 Precautions for safe handling:

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**SECTION 7: HANDLING AND STORAGE (continue)**

**A.- Precautions for safe manipulation**

Comply with the current legislation concerning the prevention of industrial risks. Keep containers hermetically sealed. Control spills and residues, destroying them with safe methods (section 6). Avoid leakages from the container. Maintain order and cleanliness where dangerous products are used.

**B.- Technical recommendations for the prevention of fires and explosions**

Due to its non-flammable nature, the product does not present a fire risk under normal conditions of storage, manipulation and use.

**C.- Technical recommendations to prevent ergonomic and toxicological risks**

Do not eat or drink during the process, washing hands afterwards with suitable cleaning products.

**D.- Technical recommendations to prevent environmental risks**

It is not necessary to take special measures to prevent environmental risks. For more information see subsection 6.2

**7.2 Conditions for safe storage, including any incompatibilities:**

**A.- Technical measures for storage**

Store in a cool, dry, well-ventilated location

**B.- General conditions for storage**

Avoid sources of heat, radiation, static electricity and contact with food. For additional information see subsection 10.5

**Other information:**

Treat and store as potentially infectious in accordance with technical data sheet

**7.3 Specific end use(s):**

REF 22013: for quality control of quantitative determination of HbA1c in human blood by Turbidimetric Immunoassay or by Enzymatic Method

REF 22052: For calibration of quantitative determination of the HbA1c in the human blood by Enzymatic Method

**SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**

**8.1 Control parameters:**

Substances whose occupational exposure limits have to be monitored in the work environment

Nuisance dust: Inhalable dust 10 mg/m<sup>3</sup> // Respirable dust 4 mg/m<sup>3</sup>

**8.2 Exposure controls:**

**A.- General security and hygiene measures in the work place**

As a preventative measure it is recommended to use basic Personal Protection Equipment, with the corresponding <<CE marking>> in accordance with Directive 89/686/EC. For more information on Personal Protection Equipment (storage, use, cleaning, maintenance, class of protection,...) consult the information leaflet provided by the manufacturer. For more information see subsection 7.1.

All information contained herein is a recommendation which needs some specification from the labour risk prevention services as it is not known whether the company has additional measures at its disposal.

**B.- Respiratory protection**

The use of protection equipment will be necessary if a mist forms or if the professional exposure limits are exceeded.

**C.- Specific protection for the hands**

Pictogram	PPE	Labelling	CEN Standard	Remarks
 Mandatory hand protection	Protective gloves against minor risks			Replace gloves in case of any sign of damage. For prolonged periods of exposure to the product for professional users/industrials, we recommend using CE III gloves in line with standards EN 420 and EN 374.

**D.- Ocular and facial protection**

Pictogram	PPE	Labelling	CEN Standard	Remarks
 Mandatory face protection	Panoramic glasses against liquid splash		EN 166:2001 EN ISO 4007:2012	Clean daily and disinfect periodically according to the manufacturer's instructions. Use if there is a risk of splashing.

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**SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION (continue)**

E.- Bodily protection

Pictogram	PPE	Labelling	CEN Standard	Remarks
	Work clothing			For professional use only.
	Anti-slip work shoes		EN ISO 20347:2012	None

F.- Additional emergency measures

It is not necessary to take additional emergency measures.

Handle in accordance with GMP and the Guide to the Correct Execution of Biomedical Analysis

**Environmental exposure controls:**

In accordance with the community legislation for the protection of the environment it is recommended to avoid environmental spillage of both the product and its container. For additional information see subsection 7.1.D

**SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**

**9.1 Information on basic physical and chemical properties:**

For complete information see the product datasheet.

**Appearance:**

Physical state at 20 °C: Solid  
 Appearance: Compact  
 Color:  Amaranth  
 Odor: Not available

**Volatility:**

Boiling point at atmospheric pressure: Non-applicable \*  
 Vapour pressure at 20 °C: Non-applicable \*  
 Vapour pressure at 50 °C: Non-applicable \*  
 Evaporation rate at 20 °C: Non-applicable \*

**Product description:**

Density at 20 °C: Non-applicable \*  
 Relative density at 20 °C: Non-applicable \*  
 Dynamic viscosity at 20 °C: Non-applicable \*  
 Kinematic viscosity at 20 °C: Non-applicable \*  
 Kinematic viscosity at 40 °C: Non-applicable \*  
 Concentration: Non-applicable \*  
 pH: Non-applicable \*  
 Vapour density at 20 °C: Non-applicable \*  
 Partition coefficient n-octanol/water 20 °C: Non-applicable \*  
 Solubility in water at 20 °C: Non-applicable \*  
 Solubility properties: Non-applicable \*  
 Decomposition temperature: Non-applicable \*  
 Melting point/freezing point: Non-applicable \*

**Flammability:**

\*Not relevant due to the nature of the product, not providing information property of its hazards.

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#### SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES (continue)

Flash Point:	Non Flammable (>60 °C)
Autoignition temperature:	Non-applicable *
Lower flammability limit:	Non-applicable *
Upper flammability limit:	Non-applicable *

#### 9.2 Other information:

Surface tension at 20 °C:	Non-applicable *
Refraction index:	Non-applicable *

\*Not relevant due to the nature of the product, not providing information property of its hazards.

#### SECTION 10: STABILITY AND REACTIVITY

##### 10.1 Reactivity:

No hazardous reactions are expected because the product is stable under recommended storage conditions. See section 7.

##### 10.2 Chemical stability:

Chemically stable under the conditions of storage, handling and use.

##### 10.3 Possibility of hazardous reactions:

Under the specified conditions, hazardous reactions that lead to excessive temperatures or pressure are not expected.

##### 10.4 Conditions to avoid:

Applicable for handling and storage at room temperature:

Shock and friction	Contact with air	Increase in temperature	Sunlight	Humidity
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable

##### 10.5 Incompatible materials:

Acids	Water	Combustive materials	Combustible materials	Others
Not applicable	Not applicable	Not applicable	Not applicable	Avoid alkalis or strong bases

Tetrachloroethylene may react with strong oxidizers and chemically active metals such as barium, lithium and berberium. Incompatible with strong acids, bases and oxidizers.

##### 10.6 Hazardous decomposition products:

See subsection 10.3, 10.4 and 10.5 to find out the specific decomposition products. Depending on the decomposition conditions, complex mixtures of chemical substances can be released: carbon dioxide (CO<sub>2</sub>), carbon monoxide and other organic compounds.

#### SECTION 11: TOXICOLOGICAL INFORMATION

##### 11.1 Information on toxicological effects:

LD50 oral > 2000 mg/kg (rat)

##### Dangerous health implications:

In case of exposure that is repetitive, prolonged or at concentrations higher than recommended by the occupational exposure limits, it may result in adverse effects on health depending on the means of exposure:

##### A.- Ingestion:

- Acute toxicity: Based on available data, the classification criteria are not met
- Corrosivity/Irritability: Based on available data, the classification criteria are not met

##### B- Inhalation:

- Acute toxicity: Based on available data, the classification criteria are not met
- Corrosivity/Irritability: Based on available data, the classification criteria are not met

##### C- Contact with the skin and the eyes:

- Contact with the skin: Based on available data, the classification criteria are not met
- Contact with the eyes: Based on available data, the classification criteria are not met

##### D- CMR effects (carcinogenicity, mutagenicity and toxicity to reproduction):

- Carcinogenicity: Based on available data, the classification criteria are not met
- Mutagenicity: Based on available data, the classification criteria are not met
- Reproductive toxicity: Based on available data, the classification criteria are not met

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#### SECTION 11: TOXICOLOGICAL INFORMATION (continue)

##### E- Sensitizing effects:

- Respiratory: Based on available data, the classification criteria are not met
- Cutaneous: Based on available data, the classification criteria are not met

##### F- Specific target organ toxicity (STOT)-time exposure:

Based on available data, the classification criteria are not met

##### G- Specific target organ toxicity (STOT)-repeated exposure:

- Specific target organ toxicity (STOT)-repeated exposure: Based on available data, the classification criteria are not met
- Skin: Based on available data, the classification criteria are not met

##### H- Aspiration hazard:

Based on available data, the classification criteria are not met

##### Other information:

it should be handled as recommended for any potentially infectious blood specimen  
chemical and toxicological properties of this product have not yet been thoroughly investigated.

Tetrachloroethylene:

C50 Inhalation- rat 4h: 5200 ppm

LC50 dermal -rabbit24h 500 mg- Mild

LC50 Orale-rat 8100 mg/Kg

##### Specific toxicology information on the substances:

Not available

#### SECTION 12: ECOLOGICAL INFORMATION

The experimental information related to the eco-toxicological properties of the product itself is not available

##### 12.1 Toxicity:

Not available

##### 12.2 Persistence and degradability:

Not available

##### 12.3 Bioaccumulative potential:

Not available

##### 12.4 Mobility in soil:

Not available

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

Non-applicable

##### 12.6 Other adverse effects:

Not described

#### SECTION 13: DISPOSAL CONSIDERATIONS

##### 13.1 Waste treatment methods:

Code	Description	Waste class (Regulation (EU) No 1357/2014)
16 03 06	Organic wastes other than those mentioned in 16 03 05	Non dangerous

##### Type of waste (Regulation (EU) No 1357/2014):

Non-applicable

##### Waste management (disposal and evaluation):

Consult the authorized waste service manager on the assessment and disposal operations in accordance with Annex 1 and Annex 2 (Directive 2008/98/EC). As under 15 01 (2014/955/EC) of the code and in case the container has been in direct contact with the product, it will be processed the same way as the actual product. Otherwise, it will be processed as non-dangerous residue. We do not recommended disposal down the drain. See paragraph 6.2.

##### Regulations related to waste management:

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#### SECTION 13: DISPOSAL CONSIDERATIONS (continue)

In accordance with Annex II of Regulation (EC) n°1907/2006 (REACH) the community or state provisions related to waste management are stated  
Community legislation: Directive 2008/98/EC, 2014/955/EU, Regulation (EU) No 1357/2014

#### SECTION 14: TRANSPORT INFORMATION

This product is not regulated for transport (ADR/RID,IMDG,IATA)

#### SECTION 15: REGULATORY INFORMATION

##### 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture:

Candidate substances for authorisation under the Regulation (EC) 1907/2006 (REACH): Non-applicable

Substances included in Annex XIV of REACH ("Authorisation List") and sunset date: Non-applicable

Regulation (EC) 1005/2009, about substances that deplete the ozone layer: Non-applicable

Article 95, REGULATION (EU) No 528/2012: Non-applicable

REGULATION (EU) No 649/2012, in relation to the import and export of hazardous chemical products: Non-applicable

##### Limitations to commercialisation and the use of certain dangerous substances and mixtures (Annex XVII, REACH):

Non-applicable

##### Specific provisions in terms of protecting people or the environment:

It is recommended to use the information included in this safety data sheet as data used in a risk evaluation of the local circumstances in order to establish the necessary risk prevention measures for the manipulation, use, storage and disposal of this product.

##### Other legislation:

The product could be affected by sectorial legislation

##### 15.2 Chemical safety assessment:

The supplier has not carried out evaluation of chemical safety.

#### SECTION 16: OTHER INFORMATION

##### Legislation related to safety data sheets:

This safety data sheet has been designed in accordance with ANNEX II-Guide to the compilation of safety data sheets of Regulation (EC) N° 1907/2006 (Regulation (EU) N° 453/2010, Regulation (EC) N° 2015/830)

##### Modifications related to the previous security card which concerns the ways of managing risks. :

Non-applicable

##### Texts of the legislative phrases mentioned in section 3:

The phrases indicated do not refer to the product itself; they are present merely for informative purposes and refer to the individual components which appear in section 3

##### Directive 67/548/EC and Directive 1999/45/EC:

Non-applicable

##### CLP Regulation (EC) n° 1272/2008:

Non-applicable

##### Classification procedure:

Non-applicable

##### Advice related to training:

Minimal training is recommended to prevent industrial risks for staff using this product, in order to facilitate their comprehension and interpretation of this safety data sheet, as well as the label on the product.

##### Principal bibliographical sources:

<http://esis.jrc.ec.europa.eu>

<http://echa.europa.eu>

<http://eur-lex.europa.eu>

##### Abbreviations and acronyms:

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#### SECTION 16: OTHER INFORMATION (continue)

ADR: European agreement concerning the international carriage of dangerous goods by road  
IMDG: International maritime dangerous goods code  
IATA: International Air Transport Association  
ICAO: International Civil Aviation Organisation  
COD: Chemical Oxygen Demand  
BOD5: 5-day biochemical oxygen demand  
BCF: Bioconcentration factor  
LD50: Lethal Dose 50  
CL50: Lethal Concentration 50  
EC50: Effective concentration 50  
Log-POW: Octanol–water partition coefficient  
Koc: Partition coefficient of organic carbon

The information contained in this safety data sheet is based on sources, technical knowledge and current legislation at European and state level, without being able to guarantee its accuracy. This information cannot be considered a guarantee of the properties of the product, it is simply a description of the security requirements. The occupational methodology and conditions for users of this product are not within our awareness or control, and it is ultimately the responsibility of the user to take the necessary measures to obtain the legal requirements concerning the manipulation, storage, use and disposal of chemical products. The information on this safety data sheet only refers to this product, which should not be used for needs other than those specified.

- END OF SAFETY DATA SHEET -