

CZ1050 - α -Galactosidase 110B, *Bacteroides fragilis*

Date of compilation: 23/06/2020

Revised: 12/10/2023

Version: 2 (Replaced 1)

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING**1.1 Product identifier:** CZ1050 - α -Galactosidase 110B, *Bacteroides fragilis*

Glycerol

CAS: 56-81-5

EC: 200-289-5

Index: Non-applicable

REACH: 01-2119471987-18-XXXX

Other means of identification:

Non-applicable

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

Relevant uses: Laboratory. For professional users 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:

NzyTech

Estrada do Paco do Lumiar Campus do Lumiar - Edif. E, r/c

1649-038 Lisboa - Lisboa - Portugal

info@nzytech.com

www.nzytech.com

1.4 Emergency telephone number: Contact Local Poison Information Center or Local Emergency Number**SECTION 2: HAZARDS IDENTIFICATION ******2.1 Classification of the substance or mixture:****CLP Regulation (EC) No 1272/2008:**

Classification of this product has been carried out in accordance with CLP Regulation (EC) No 1272/2008.

Eye Irrit. 2: Eye irritation, Category 2, H319

Repr. 1B: Reproductive toxicity, Category 1B, H360D

Skin Irrit. 2: Skin irritation, Category 2, H315

2.2 Label elements:**CLP Regulation (EC) No 1272/2008:**

Labelling of packages where the contents do not exceed 125 ml:

Danger**Hazard statements:**

Repr. 1B: H360D - May damage the unborn child.

Precautionary statements:

P201: Obtain special instructions before use.

P280: Wear protective gloves/face protection/protective clothing/respiratory protection/protective footwear.

P308+P313: IF exposed or concerned: Get medical advice/attention.

P501: Dispose of contents/container in accordance with regulations on hazardous waste or packaging and packaging waste respectively.

Substances that contribute to the classification

Imidazole (CAS: 288-32-4)

Additional Labelling:

Restricted to professional users

2.3 Other hazards:

** Changes with regards to the previous version

- CONTINUED ON NEXT PAGE -

CZ1050 - α -Galactosidase 110B, *Bacteroides fragilis*

Date of compilation: 23/06/2020

Revised: 12/10/2023

Version: 2 (Replaced 1)

SECTION 2: HAZARDS IDENTIFICATION ** (continued)

Product does not meet PBT/vPvB criteria
Endocrine-disrupting properties: The product does not meet the criteria.

** Changes with regards to the previous version

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substance:

Chemical description: Mixture of substances

Components:

In accordance with Annex II of Regulation (EC) No 1907/2006 (point 3), the product contains:

Identification	Chemical name/Classification	Concentration
CAS: 288-32-4 EC: 206-019-2 Index: Non-applicable REACH: 01-2119485825-24-XXXX	Imidazole⁽¹⁾ Regulation 1272/2008 Acute Tox. 4: H302; Eye Dam. 1: H318; Repr. 1B: H360D; Skin Corr. 1C: H314 - Danger	Self-classified  1 - <2,5 %

⁽¹⁾ Substances presenting a health or environmental hazard which meet criteria laid down in Regulation (EU) No. 2020/878

To obtain more information on the hazards of the substances consult sections 11, 12 and 16.

3.2 Mixture:

Non-applicable

Acute toxicity estimate for the substance in Part 3 of Annex VI to Regulation (EC) No 1272/2008 or as determined in accordance with Annex I to that Regulation:

Identification	Acute toxicity		Genus
Imidazole	LD50 oral	500 mg/kg (ATEI)	
CAS: 288-32-4	LD50 dermal	Non-applicable	
EC: 206-019-2	LC50 inhalation	Non-applicable	

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures:

The symptoms resulting from intoxication can appear after exposure, therefore, in case of doubt, seek medical attention for direct exposure to the chemical product or persistent discomfort, showing the SDS of this product.

By inhalation:

This product does not contain substances classified as hazardous for inhalation, however, in case of symptoms of intoxication remove the person affected from the exposure area and provide with fresh air. Seek medical attention if the symptoms get worse or persist.

By skin contact:

Remove contaminated clothing and footwear, rinse skin or shower the person affected if appropriate with plenty of cold water and neutral soap. In serious cases see a doctor. If the product causes burns or freezing, clothing should not be removed as this could worsen the injury caused if it is stuck to the skin. If blisters form on the skin, these should never be burst as this will increase the risk of infection.

By eye contact:

Rinse eyes thoroughly with lukewarm water for at least 15 minutes. Do not allow the person affected to rub or close their eyes. If the injured person uses contact lenses, these should be removed unless they are stuck to the eyes, in which case this could cause further damage. In all cases, after cleaning, a doctor should be consulted as quickly as possible with the SDS of the product.

By ingestion/aspiration:

Do not induce vomiting, but if it does happen keep the head down to avoid aspiration. Keep the person affected at rest. Rinse out the mouth and throat, as they may have been affected during ingestion.

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:

- CONTINUED ON NEXT PAGE -

CZ1050 - α -Galactosidase 110B, *Bacteroides fragilis*

Date of compilation: 23/06/2020

Revised: 12/10/2023

Version: 2 (Replaced 1)

SECTION 4: FIRST AID MEASURES (continued)

Non-applicable

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media:

Suitable extinguishing media:

Product is non-flammable under normal conditions of storage, handling and use. In the case of combustion as a result of improper handling, storage or use preferably use polyvalent powder extinguishers (ABC powder), in accordance with the Regulation on fire protection systems.

Unsuitable extinguishing media:

Non-applicable

5.2 Special hazards arising from the substance or mixture:

As a result of combustion or thermal decomposition reactive sub-products are created that can become highly toxic and, consequently, can present a serious health risk.

5.3 Advice for firefighters:

Depending on the magnitude of the fire it may be necessary to use full protective clothing and self-contained breathing apparatus (SCBA). 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. Eliminate all sources of ignition. In case of fire, cool the storage containers and tanks for products susceptible to combustion, 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:

For non-emergency personnel:

Isolate leaks provided that there is no additional risk for the people performing this task. Personal protection equipment must be used against potential contact with the spilt product (See section 8). Evacuate the area and keep out those who do not have protection.

For emergency responders:

Wear protective equipment. Keep unprotected persons away. See section 8.

6.2 Environmental precautions:

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

6.3 Methods and material for containment and cleaning up:

It is recommended:

Absorb the spillage using sand or inert absorbent and move it to a safe place. Do not absorb in sawdust or other combustible absorbents. For any concern related to disposal consult section 13.

6.4 Reference to other sections:

See sections 8 and 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling:

A.- General precautions for safe use

Comply with the current legislation concerning the prevention of industrial risks with regards manually handling weights. Maintain order, cleanliness and dispose of using safe methods (section 6).

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

- CONTINUED ON NEXT PAGE -

CZ1050 - α -Galactosidase 110B, *Bacteroides fragilis*

Date of compilation: 23/06/2020

Revised: 12/10/2023

Version: 2 (Replaced 1)

SECTION 7: HANDLING AND STORAGE (continued)

Product is non-flammable under normal conditions of storage, handling and use. It is recommended to transfer at slow speeds to avoid the generation of electrostatic charges that can affect flammable products. Consult section 10 for information on conditions and materials that should be avoided.

C.- Technical recommendations on general occupational hygiene

PREGNANT WOMEN SHOULD NOT BE EXPOSED TO THIS PRODUCT. Transfer in designated areas that comply with the necessary safety conditions (emergency showers and eyewash stations in close proximity), using personal protection equipment, especially on the hands and face (See section 8). Limit manual transfers to small amounts only. Do not eat or drink during the process, washing hands afterwards with suitable cleaning products.

D.- Technical recommendations to prevent environmental risks

It is recommended to have absorbent material available at close proximity to the product (See subsection 6.3)

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

7.3 Specific end use(s):

Except for the instructions already specified it is not necessary to provide any special recommendation regarding the uses of this product.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters:

Substances whose occupational exposure limits have to be monitored in the workplace (European OEL, not country-specific legislation):

There are no applicable occupational exposure limits for the substances contained in the product

DNEL (Workers):

Identification		Short exposure		Long exposure	
		Systemic	Local	Systemic	Local
Imidazole CAS: 288-32-4 EC: 206-019-2	Oral	Non-applicable	Non-applicable	Non-applicable	Non-applicable
	Dermal	Non-applicable	Non-applicable	1,5 mg/kg	Non-applicable
	Inhalation	Non-applicable	Non-applicable	10,6 mg/m ³	Non-applicable

DNEL (General population):

Non-applicable

PNEC:

Identification				
Imidazole CAS: 288-32-4 EC: 206-019-2	STP	10 mg/L	Fresh water	0,13 mg/L
	Soil	0,043 mg/kg	Marine water	0,013 mg/L
	Intermittent	1,3 mg/L	Sediment (Fresh water)	0,336 mg/kg
	Oral	Non-applicable	Sediment (Marine water)	0,034 mg/kg

8.2 Exposure controls:

A.- Individual protection measures, such as personal protective equipment

As a preventative measure it is recommended to use basic Personal Protective Equipment, with the corresponding <<CE marking>> in accordance with Regulation (EU) 2016/425. For more information on Personal Protective 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

- CONTINUED ON NEXT PAGE -

CZ1050 - α -Galactosidase 110B, *Bacteroides fragilis*

Date of compilation: 23/06/2020

Revised: 12/10/2023

Version: 2 (Replaced 1)

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION (continued)

Pictogram	PPE	Labelling	CEN Standard	Remarks
 Mandatory respiratory tract protection	Filter mask for gases and vapours		EN 405:2002+A1:2010	Replace when there is a taste or smell of the contaminant inside the face mask. If the contaminant comes with warnings it is recommended to use isolation equipment.

C.- Specific protection for the hands

Pictogram	PPE	Labelling	CEN Standard	Remarks
 Mandatory hand protection	Chemical protective gloves (Material: PVC, Breakthrough time: > 480 min, Thickness: 0.7 mm)		EN ISO 21420:2020	Replace the gloves at any sign of deterioration.

D.- Eye and face protection

Pictogram	PPE	Labelling	CEN Standard	Remarks
 Mandatory face protection	Face shield		EN 166:2002 EN 167:2002 EN 168:2002 EN ISO 4007:2018	Clean daily and disinfect periodically according to the manufacturer's instructions. Use if there is a risk of splashing.

E.- Body protection

Pictogram	PPE	Labelling	CEN Standard	Remarks
 Mandatory complete body protection	Disposable clothing for protection against chemical risks		EN 13034:2005+A1:2009 EN 168:2002 EN ISO 13982-1:2004/A1:2010 EN ISO 6529:2013 EN ISO 6530:2005 EN 464:1994	For professional use only. Clean periodically according to the manufacturer's instructions.
 Mandatory foot protection	Safety footwear for protection against chemical risk		EN ISO 20345:2011 EN 13832-1:2019	Replace boots at any sign of deterioration.

F.- Additional emergency measures

Emergency measure	Standards	Emergency measure	Standards
 Emergency shower	ANSI Z358-1 ISO 3864-1:2011, ISO 3864-4:2011	 Eyewash stations	DIN 12 899 ISO 3864-1:2011, ISO 3864-4:2011

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

Volatile organic compounds:

With regard to Directive 2010/75/EU, this product has the following characteristics:

V.O.C. (Supply):	0 % weight
V.O.C. density at 20 °C:	0 kg/m ³ (0 g/L)
Average carbon number:	Non-applicable
Average molecular weight:	Non-applicable

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties:

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

- CONTINUED ON NEXT PAGE -

CZ1050 - α -Galactosidase 110B, *Bacteroides fragilis*

Date of compilation: 23/06/2020

Revised: 12/10/2023

Version: 2 (Replaced 1)

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES (continued)

For complete information see the product datasheet.

Appearance:

Physical state at 20 °C:	Liquid
Appearance:	Not available
Colour:	Colourless
Odour:	Odourless
Odour threshold:	Non-applicable *

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:	1110,8 kg/m ³
Relative density at 20 °C:	1,111
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:	7,2
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:

Flash Point:	Non Flammable (>60 °C)
Flammability (solid, gas):	Non-applicable *
Autoignition temperature:	480 °C
Lower flammability limit:	Non-applicable *
Upper flammability limit:	Non-applicable *

Particle characteristics:

Median equivalent diameter:	Non-applicable
-----------------------------	----------------

9.2 Other information:

Information with regard to physical hazard classes:

Explosive properties:	Non-applicable *
Oxidising properties:	Non-applicable *
Corrosive to metals:	Non-applicable *
Heat of combustion:	Non-applicable *
Aerosols-total percentage (by mass) of flammable components:	Non-applicable *

Other safety characteristics:

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

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

- CONTINUED ON NEXT PAGE -

CZ1050 - α -Galactosidase 110B, *Bacteroides fragilis*

Date of compilation: 23/06/2020

Revised: 12/10/2023

Version: 2 (Replaced 1)

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES (continued)

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 from Safety Data Sheet.

10.2 Chemical stability:

Chemically stable under the indicated 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	Oxidising materials	Combustible materials	Others
Avoid strong acids	Not applicable	Precaution	Not applicable	Avoid alkalis or strong bases

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 (CO₂), carbon monoxide and other organic compounds.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008:

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

Dangerous health implications:

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

A- Ingestion (acute effect):

- Acute toxicity: Based on available data, the classification criteria are not met, however, it contains substances classified as dangerous for consumption. For more information see section 3.
- Corrosivity/Irritability: The consumption of a considerable dose can cause irritation in the throat, abdominal pain, nausea and vomiting.

B- Inhalation (acute effect):

- Acute toxicity : Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for inhalation. For more information see section 3.
- Corrosivity/Irritability: Based on available data, the classification criteria are not met. However, it does contain substances classified as hazardous for this effect. For more information see section 3.

C- Contact with the skin and the eyes (acute effect):

- Contact with the skin: Produces skin inflammation.
- Contact with the eyes: Produces eye damage after contact.

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

- Carcinogenicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for the effects mentioned. For more information see section 3.
IARC: Non-applicable
- Mutagenicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.
- Reproductive toxicity: May damage the unborn child.

- CONTINUED ON NEXT PAGE -

CZ1050 - α -Galactosidase 110B, *Bacteroides fragilis*

Date of compilation: 23/06/2020

Revised: 12/10/2023

Version: 2 (Replaced 1)

SECTION 11: TOXICOLOGICAL INFORMATION (continued)

E- Sensitizing effects:

- Respiratory: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous with sensitising effects. For more information see section 3.
- Skin: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.

F- Specific target organ toxicity (STOT) - single exposure:

Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.

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, as it does not contain substances classified as hazardous for this effect. For more information see section 3.
- Skin: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.

H- Aspiration hazard:

Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.

Other information:

Non-applicable

Specific toxicology information on the substances:

Identification	Acute toxicity		Genus
	LD50 oral	500 mg/kg (ATEi)	
Imidazole	LD50 dermal	>2000 mg/kg	
CAS: 288-32-4	LCS0 inhalation	>5 mg/L	
EC: 206-019-2			

11.2 Information on other hazards:

Endocrine disrupting properties

Endocrine-disrupting properties: The product does not meet the criteria.

Other information

Non-applicable

SECTION 12: ECOLOGICAL INFORMATION

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

Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.

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:

Product does not meet PBT/vPvB criteria

12.6 Endocrine disrupting properties:

Endocrine-disrupting properties: The product does not meet the criteria.

12.7 Other adverse effects:

Not described

- CONTINUED ON NEXT PAGE -

CZ1050 - α -Galactosidase 110B, *Bacteroides fragilis*

Date of compilation: 23/06/2020

Revised: 12/10/2023

Version: 2 (Replaced 1)

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods:

Code	Description	Waste class (Regulation (EU) No 1357/2014)
	It is not possible to assign a specific code, as it depends on the intended use by the user	Dangerous

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

HP10 Toxic for reproduction

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. Waste should not be disposed of to drains. See paragraph 6.2.

Regulations related to waste management:

In accordance with Annex II of Regulation (EC) No 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

Transport of dangerous goods by land:

With regard to ADR 2023 and RID 2023:

- 14.1 UN number or ID number:** Non-applicable
- 14.2 UN proper shipping name:** Non-applicable
- 14.3 Transport hazard class(es):** Non-applicable
- Labels: Non-applicable
- 14.4 Packing group:** Non-applicable
- 14.5 Environmental hazards:** No
- 14.6 Special precautions for user**
- Special regulations: Non-applicable
- Tunnel restriction code: Non-applicable
- Physico-Chemical properties: see section 9
- Limited quantities: Non-applicable
- 14.7 Maritime transport in bulk according to IMO instruments:** Non-applicable

Transport of dangerous goods by sea:

With regard to IMDG 40-20:

- 14.1 UN number or ID number:** Non-applicable
- 14.2 UN proper shipping name:** Non-applicable
- 14.3 Transport hazard class(es):** Non-applicable
- Labels: Non-applicable
- 14.4 Packing group:** Non-applicable
- 14.5 Marine pollutant:** No
- 14.6 Special precautions for user**
- Special regulations: Non-applicable
- EmS Codes:
- Physico-Chemical properties: see section 9
- Limited quantities: Non-applicable
- Segregation group: Non-applicable
- 14.7 Maritime transport in bulk according to IMO instruments:** Non-applicable

Transport of dangerous goods by air:

- CONTINUED ON NEXT PAGE -

CZ1050 - α -Galactosidase 110B, *Bacteroides fragilis*

Date of compilation: 23/06/2020

Revised: 12/10/2023

Version: 2 (Replaced 1)

SECTION 14: TRANSPORT INFORMATION (continued)

With regard to IATA/ICAO 2023:

14.1 UN number or ID number:	Non-applicable
14.2 UN proper shipping name:	Non-applicable
14.3 Transport hazard class(es):	Non-applicable
Labels:	Non-applicable
14.4 Packing group:	Non-applicable
14.5 Environmental hazards:	No
14.6 Special precautions for user	
Physico-Chemical properties:	see section 9
14.7 Maritime transport in bulk according to IMO instruments:	Non-applicable

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) No 1907/2006 (REACH): Non-applicable
 Substances included in Annex XIV of REACH ("Authorisation List") and sunset date: Non-applicable
 Regulation (EC) No 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

Seveso III:

Non-applicable

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

Product classified hazardous under the CMR. Sale and distribution to the general public is prohibited. Due to its CMR category, it is essential to apply the specific measures for workplace hazard prevention covered in articles 4 and 5 of the 2004/37/EC Directive and later modifications.

Shall not be used in:

- ornamental articles intended to produce light or colour effects by means of different phases, for example in ornamental lamps and ashtrays,
- tricks and jokes,
- games for one or more participants, or any article intended to be used as such, even with ornamental aspects.

Specific provisions in terms of protecting people or the environment:

It is recommended to use the information included in this safety data sheet as a basis for conducting workplace-specific risk assessments in order to establish the necessary risk prevention measures for the handling, 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:

The SDS shall be supplied in an official language of the country where the product is placed on the market. This safety data sheet has been designed in accordance with ANNEX II-Guide to the compilation of safety data sheets of Regulation (EC) No 1907/2006 (COMMISSION REGULATION (EU) 2020/878).

Modifications related to the previous Safety Data Sheet which concerns the ways of managing risks.:

** Changes with regards to the previous version

- CONTINUED ON NEXT PAGE -

CZ1050 - α -Galactosidase 110B, *Bacteroides fragilis*

Date of compilation: 23/06/2020

Revised: 12/10/2023

Version: 2 (Replaced 1)

SECTION 16: OTHER INFORMATION ** (continued)

COMMISSION REGULATION (EU) 2020/878

CLP Regulation (EC) No 1272/2008 (SECTION 2, SECTION 16):

· Hazard statements

Texts of the legislative phrases mentioned in section 2:

H315: Causes skin irritation.

H360D: May damage the unborn child.

H319: Causes serious eye irritation.

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

CLP Regulation (EC) No 1272/2008:

Acute Tox. 4: H302 - Harmful if swallowed.

Eye Dam. 1: H318 - Causes serious eye damage.

Repr. 1B: H360D - May damage the unborn child.

Skin Corr. 1C: H314 - Causes severe skin burns and eye damage.

Advice related to training:

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

Principal bibliographical sources:

<http://echa.europa.eu>

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

Abbreviations and acronyms:

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: 5day biochemical oxygen demand

BCF: Bioconcentration factor

LD50: Lethal Dose 50

LC50: Lethal Concentration 50

EC50: Effective concentration 50

LogPOW: Octanolwater partition coefficient

Koc: Partition coefficient of organic carbon

UFI: unique formula identifier

IARC: International Agency for Research on Cancer

*** Changes with regards to the previous version*

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.

- CONTINUED ON NEXT PAGE -