Safety data sheet legislation

This SDS is an English translation of COMMISSION REGULATION (EU) 2020/878, without any country-specific NZYtech

CZ0961 - Isoamylase 13A, Escherichia coli

Date of	compilation: 23/06/202	20 Revised: 12/10/2023	Version: 2 (Replaced 1)
SECT	TION 1: IDENTIFIC	ATION OF THE SUBSTANCE/MIX	TURE AND OF THE COMPANY/UNDERTAKING
1.1	Product identifier:	CZ0961 - Isoamylase 13A, Escherici	hia coli
		Glycerol	
	CAS:	56-81-5	
	EC:	200-289-5	
	Index:	Non-applicable	
	REACH:	01-2119471987-18-XXXX	
	Other means of ide	entification:	
	Non-applicable		
1.2	Relevant identified	l uses of the substance or mixture	e and uses advised against:
	Relevant uses: Labor	atory. For professional users only.	
	Uses advised against	: All uses not specified in this section	or in section 7.3
1.3	Details of the supp	plier of the safety data sheet:	
	NZYTech Estrada do Paco do L 1649-038 Lisboa - Li info@nzytech.com www.nzytech.com	umiar Campus do Lumiar - Edif. E, r/c sboa - Portugal	
1.4	Emergency telepho	one number: Contact Local Poison I	Information Center or Local Emergency Number
SECT	TION 2: HAZARDS I	DENTIFICATION **	
2.1	Classification of th	e substance or mixture:	
	CLP Regulation (F	C) No 1272/2008:	

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

Label elements: 2.2

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

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SECTION 2: HAZARDS IDENTIFICATION ** (continued)

Product does not meet PBT/vPvB criteria

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

Revised: 12/10/2023

** 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			
CAS:	288-32-4	Imidazole ⁽¹⁾		Self-classified		
EC: Index: REACH:	206-019-2 Non-applicable 01-2119485825-24- XXXX	Regulation 1272/2008	Acute Tox. 4: H302; Eye Dam. 1: H318; Repr. 1B: H360D; Skin Corr. 1C: H314 - Danger	(I) (I) (I) (I) (I) (I) (I) (I) (I) (I)	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	Acu	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:

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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



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ofo	compilation: 23/06/2020	Revised: 12/10/20)23 Ve	ersion: 2 (Replace	d 1)		
ECT	TON 7: HANDLING AND	STORAGE (continu	ed)				
	Product is non-flammat to avoid the generatior conditions and material C Technical recommendat PREGNANT WOMEN SH necessary safety condit	n of electrostatic char Is that should be avoi tions on general occup IOULD NOT BE EXPO	ges that can a ded. pational hygien SED TO THIS	ffect flammable p e PRODUCT. Trans	products. Consul fer in designated	lt section 10 foi d areas that coi	r information on mply with the
	equipment, especially c drink during the proces D Technical recommendat	ss, washing hands aft	erwards with s			amounts only.	Do not eat or
	It is recommended to h	ave absorbent materi	al available at o	close proximity to	the product (Se	e subsection 6.	3)
2	Conditions for safe stora	age, including any i	ncompatibiliti	es:			
	A Technical measures for	storage					
	Store in a cool, dry, wel	I-ventilated location					
	B General conditions for	storage					
	Avoid sources of heat, r	radiation, static electri	city and conta	t with food. For a	additional inform	ation see subse	ection 10.5
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.						
ECT	TON 8: EXPOSURE CONT Control parameters: Substances whose occupat legislation):	TROLS/PERSONAL	PROTECTION	N Nitored in the wor	kplace (Europea		ntry-specific
	TON 8: EXPOSURE CON Control parameters: Substances whose occupat	TROLS/PERSONAL	PROTECTION	N Nitored in the wor	kplace (Europea		ntry-specific
	TON 8: EXPOSURE CON Control parameters: Substances whose occupat legislation): There are no applicable occ	TROLS/PERSONAL	PROTECTION	N hitored in the wor pstances containe	kplace (Europea	:	ntry-specific g exposure
	TON 8: EXPOSURE CON Control parameters: Substances whose occupat legislation): There are no applicable occ	TROLS/PERSONAL ional exposure limits l	PROTECTION have to be mor mits for the sul	N hitored in the wor pstances containe Short Systemic	kplace (Europea ed in the product exposure Local	Lon Systemic	g exposure
	product. TON 8: EXPOSURE CONT Control parameters: Substances whose occupat legislation): There are no applicable occ DNEL (Workers): Identifica Imidazole	TROLS/PERSONAL ional exposure limits l	PROTECTION have to be mor mits for the sul	N hitored in the wor postances containe Short Systemic Non-applicable	kplace (Europea ed in the product exposure Local Non-applicable	Lon Systemic Non-applicable	g exposure Local Non-applicable
	product. TON 8: EXPOSURE CON Control parameters: Substances whose occupat legislation): There are no applicable occ DNEL (Workers): Identifica Imidazole CAS: 288-32-4	TROLS/PERSONAL ional exposure limits l	PROTECTION nave to be mor mits for the sul Oral Dermal	N hitored in the wor postances containe Short Systemic Non-applicable Non-applicable	kplace (Europea ed in the product exposure Local Non-applicable Non-applicable	Lon Systemic Non-applicable 1,5 mg/kg	g exposure Local Non-applicable Non-applicable
	product. TON 8: EXPOSURE CONT Control parameters: Substances whose occupat legislation): There are no applicable occ DNEL (Workers): Identifica Imidazole CAS: 288-32-4 EC: 206-019-2	TROLS/PERSONAL ional exposure limits l cupational exposure limits	PROTECTION have to be mor mits for the sul	N hitored in the wor postances containe Short Systemic Non-applicable	kplace (Europea ed in the product exposure Local Non-applicable	Lon Systemic Non-applicable	g exposure Local Non-applicable
_	product. TON 8: EXPOSURE CON Control parameters: Substances whose occupat legislation): There are no applicable occ DNEL (Workers): Identifica Imidazole CAS: 288-32-4 EC: 206-019-2 DNEL (General population	TROLS/PERSONAL ional exposure limits l cupational exposure limits	PROTECTION nave to be mor mits for the sul Oral Dermal	N hitored in the wor postances containe Short Systemic Non-applicable Non-applicable	kplace (Europea ed in the product exposure Local Non-applicable Non-applicable	Lon Systemic Non-applicable 1,5 mg/kg	g exposure Local Non-applicable Non-applicable
	product. TON 8: EXPOSURE CONT Control parameters: Substances whose occupat legislation): There are no applicable occ DNEL (Workers): Identifica Imidazole CAS: 288-32-4 EC: 206-019-2 DNEL (General population Non-applicable	TROLS/PERSONAL ional exposure limits l cupational exposure limits	PROTECTION nave to be mor mits for the sul Oral Dermal	N hitored in the wor postances containe Short Systemic Non-applicable Non-applicable	kplace (Europea ed in the product exposure Local Non-applicable Non-applicable	Lon Systemic Non-applicable 1,5 mg/kg	g exposure Local Non-applicable Non-applicable
	product. TON 8: EXPOSURE CON Control parameters: Substances whose occupat legislation): There are no applicable occ DNEL (Workers): Identifica Imidazole CAS: 288-32-4 EC: 206-019-2 DNEL (General population	TROLS/PERSONAL ional exposure limits l cupational exposure limits ation	PROTECTION nave to be mor mits for the sul Oral Dermal	N hitored in the wor postances containe Short Systemic Non-applicable Non-applicable	kplace (Europea ed in the product exposure Local Non-applicable Non-applicable	Lon Systemic Non-applicable 1,5 mg/kg	g exposure Local Non-applicable Non-applicable
	product. TON 8: EXPOSURE CON Control parameters: Substances whose occupat legislation): There are no applicable occ DNEL (Workers): Identifica Imidazole CAS: 288-32-4 EC: 206-019-2 DNEL (General population Non-applicable PNEC:	TROLS/PERSONAL ional exposure limits l cupational exposure limits ation	PROTECTION nave to be mor mits for the sul Oral Dermal	N hitored in the wor postances containe Short Systemic Non-applicable Non-applicable	kplace (Europea ed in the product exposure Local Non-applicable Non-applicable	Lon Systemic Non-applicable 1,5 mg/kg 10,6 mg/m ³	g exposure Local Non-applicable Non-applicable
	product. TON 8: EXPOSURE CON Control parameters: Substances whose occupat legislation): There are no applicable occ DNEL (Workers): Identifica Imidazole CAS: 288-32-4 EC: 206-019-2 DNEL (General population Non-applicable PNEC: Identifica	TROLS/PERSONAL ional exposure limits l cupational exposure limits ation	PROTECTION have to be mor mits for the sul Oral Dermal Inhalation	N hitored in the wor postances containe Short Systemic Non-applicable Non-applicable	kplace (Europea ed in the product exposure Local Non-applicable Non-applicable	Lon Systemic Non-applicable 1,5 mg/kg 10,6 mg/m ³	g exposure Local Non-applicable Non-applicable Non-applicable
	product. TON 8: EXPOSURE CON Control parameters: Substances whose occupat legislation): There are no applicable occ DNEL (Workers): Identifica Imidazole CAS: 288-32-4 EC: 206-019-2 DNEL (General population Non-applicable PNEC: Identifica Imidazole	TROLS/PERSONAL ional exposure limits l cupational exposure limits ation	PROTECTION have to be mor mits for the sul Oral Dermal Inhalation	N hitored in the wor ostances containe Short Non-applicable Non-applicable Non-applicable 10 mg/L 0,043 mg/kg 1,3 mg/L	kplace (Europea ed in the product exposure Local Non-applicable Non-applicable Non-applicable	Lon Systemic Non-applicable 1,5 mg/kg 10,6 mg/m ³	g exposure Local Non-applicable Non-applicable Non-applicable 0,13 mg/L 0,013 mg/L 0,336 mg/kg
1	product. TON 8: EXPOSURE CON Control parameters: Substances whose occupat legislation): There are no applicable occ DNEL (Workers): Identifica Imidazole CAS: 288-32-4 EC: 206-019-2 DNEL (General population Non-applicable PNEC: Identifica Imidazole CAS: 288-32-4 EC: 206-019-2	TROLS/PERSONAL ional exposure limits l cupational exposure limits ation	PROTECTION have to be mor mits for the sul Oral Dermal Inhalation	N hitored in the wor ostances containe Short Non-applicable Non-applicable Non-applicable Non-applicable	kplace (Europea ed in the product exposure <u>Local</u> Non-applicable Non-applicable Non-applicable	Lon Systemic Non-applicable 1,5 mg/kg 10,6 mg/m ³	g exposure Local Non-applicable Non-applicable Non-applicable
	product. TON 8: EXPOSURE CON Control parameters: Substances whose occupat legislation): There are no applicable occ DNEL (Workers): Identifica Imidazole CAS: 288-32-4 EC: 206-019-2 DNEL (General population Non-applicable PNEC: Identifica Imidazole CAS: 288-32-4 EC: 206-019-2	IROLS/PERSONAL ional exposure limits l cupational exposure lim ation on):	PROTECTION have to be mor mits for the sul Oral Dermal Inhalation	N hitored in the wor ostances containe Short Systemic Non-applicable Non-applicable Non-applicable 10 mg/L 0,043 mg/kg 1,3 mg/L Non-applicable	kplace (Europea ed in the product exposure Local Non-applicable Non-applicable Non-applicable Fresh water Marine water Sediment (Frest	Lon Systemic Non-applicable 1,5 mg/kg 10,6 mg/m ³	g exposure Local Non-applicable Non-applicable Non-applicable 0,13 mg/L 0,013 mg/L 0,336 mg/kg

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TION	8: EXPOSURE	CONTROLS/PERS	SONAL PROTEC	TION (c	ontinued)		
	Pictogram	PPE	Labelling		CEN Standard		Remarks
	Mandatory respiratory tract protection	Filter mask for gases vapours	and CAT III	EN	405:2002+A1:2010	C	place when there is a taste or smell of the ontaminant inside the face mask. If the contaminant comes with warnings it is commended to use isolation equipment.
C	Specific protection	n for the hands					
	Pictogram	PPE	Labelling		CEN Standard		Remarks
	Mandatory hand protection	Chemical protective ((Material: PVC, Breakth time: > 480 min, Thick 0.7 mm)	nrough	E	N ISO 21420:2020	Repl	ace the gloves at any sign of deterioration
D	Eye and face prot	ection					
	Pictogram	PPE	Labelling		CEN Standard		Remarks
	Mandatory face protection	Face shield	CAT II	E	EN 166:2002 EN 167:2002 EN 168:2002 N ISO 4007:2018		a daily and disinfect periodically according aanufacturer´s instructions. Use if there is risk of splashing.
E	Body protection						
	Pictogram	PPE	Labelling		CEN Standard		Remarks
	Mandatory complete body protection	Disposable clothing protection against che risks		E	3034:2005+A1:2009 EN 168:2002 EN 15O 13982- 1:2004/A1:2010 N ISO 6529:2013 N ISO 6530:2005 EN 464:1994		r professional use only. Clean periodically ording to the manufacturer's instructions.
	Mandatory foot protection	Safety footwear f protection against che risk			N ISO 20345:2011 N 13832-1:2019	Re	eplace boots at any sign of deterioration.
F	Additional emerge	ency measures					
	Emergency mea	asure	Standards		Emergency measu	ıre	Standards
	Emergency sho		ANSI Z358-1 64-1:2011, ISO 3864-4	:2011	Eyewash station	IS	DIN 12 899 ISO 3864-1:2011, ISO 3864-4:2011
En	vironmental exp	osure controls:					
In a spil	accordance with th	ne community legisl product and its cont					nmended to avoid environmental D
Wit	h regard to Direct	ive 2010/75/EU, thi	is product has the f	following	characteristics:		
	V.O.C. (Supply):		0 % weight				
	V.O.C. density at	20 ºC:	0 kg/m ³ (0 g/L)				
	Average carbon r	number:	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.

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SECT	TON 9: PHYSICAL AND CHEMICAL PROPERTIES	G (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/m³
	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: Particle characteristics:	Non-applicable *
		Non applicable
9.2	Median equivalent diameter: Other information:	Non-applicable
5.2	Information with regard to physical hazard class	
	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	Non-applicable *
	components:	· · · · · · · · · · · · · · · · · · ·
	Other safety characteristics:	
	Surface tension at 20 °C:	Non-applicable *
	*Not relevant due to the nature of the product, not providing infor	mation property of its hazards.

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SECT	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.						
CECT							
SECT	ION 10: STABILITY AND	REACTIVITY					
10.1	Reactivity:						
10.2	No hazardous reactions are expected because the product is stable under recommended storage conditions. See section 7 from Safety Data Sheet.						
10.2		indicated and ditions of a					
	Chemically stable under the	indicated conditions of st	corage, handling and use.				
10.3	Possibility of hazardous	reactions:					
	Under the specified condition	ons, hazardous reactions t	hat lead to excessive temp	peratures or pressure are r	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.



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	compilation: 23/06/2020			eplaced 1)			
SECT	ION 11: TOXICOLOGICA	L INFORMATION (conti	nued)				
	E- Sensitizing effects:						
	hazardous with sensitisi - Skin: Based on availa	n available data, the classifi ng effects. For more inforn ble data, the classification o t. For more information sec icity (STOT) - single exposi	nation see section 3 criteria are not met, e section 3.	3.			
	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:						
	it does not contain subs - Skin: Based on availa	toxicity (STOT)-repeated e tances classified as hazard ble data, the classification o t. For more information see	ous for this effect. I criteria are not met,	For more informa	tion see section 3.		
Based on available data, the classification criteria are not met, as it does not contain substances classified as hazard this effect. For more information see section 3. Other information:					zardous for		
	Non-applicable						
	Specific toxicology inform	nation on the substances	S:				
		Identification		Ac	ute toxicity	Genus	
	Imidazole			LD50 oral	500 mg/kg (ATEi)		
	CAS: 288-32-4			LD50 dermal	>2000 mg/kg		
	EC: 206-019-2						
				LC50 inhalation	>5 mg/L		
11.2	Information on other ha	zards:		LC50 inhalation	>5 mg/L		
11.2				LC50 inhalation	>5 mg/L		
11.2	Information on other ha	perties	meet the criteria.	LC50 inhalation	>5 mg/L		
11.2	Information on other ha Endocrine disrupting pro	perties	meet the criteria.	LC50 inhalation	>5 mg/L		
11.2	Information on other ha Endocrine disrupting pro Endocrine-disrupting proper	perties	meet the criteria.	LC50 inhalation	>5 mg/L		
11.2	Information on other ha Endocrine disrupting pro Endocrine-disrupting proper Other information	perties	meet the criteria.	LC50 inhalation	>5 mg/L		
	Information on other ha Endocrine disrupting pro Endocrine-disrupting proper Other information Non-applicable	perties ties: The product does not r	meet the criteria.	LC50 inhalation	>5 mg/L		
SECT	Information on other ha Endocrine disrupting pro Endocrine-disrupting proper Other information Non-applicable ION 12: ECOLOGICAL IN	perties ties: The product does not r FORMATION					
SECT. The ex	Information on other ha Endocrine disrupting pro Endocrine-disrupting proper Other information Non-applicable ION 12: ECOLOGICAL IN xperimental information related	perties ties: The product does not r FORMATION ed to the eco-toxicological p	properties of the pro	duct itself is not a	available		
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Revised: 12/10/2023



This SDS is an English translation of COMMISSION REGULATION (EU) 2020/878, without any country-specific

legislation

CZ0961 - Isoamylase 13A, Escherichia coli

Date of compilation: 23/06/2020

Revised: 12/10/2023

Version: 2 (Replaced 1)

13.1 Waste treatment methods:

SECTION 13: DISPOSAL CONSIDERATIONS

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:

14.2 14.3 14.4 14.5	Labels: Packing group: Environmental hazards: Special precautions for user Special regulations: Tunnel restriction code: Physico-Chemical properties:	Non-applicable Non-applicable Non-applicable Non-applicable No Non-applicable Non-applicable see section 9
14.7	Limited quantities: Maritime transport in bulk according to IMO instruments:	Non-applicable Non-applicable
Transpo	rt of dangerous goods by sea:	
With rega	ard 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
Transpo	rt of dangerous goods by air:	

Revised: 12/10/2023

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CZ0961 - Isoamylase 13A, Escherichia coli

Date of compilation:	23/06/2020 Revised: 12/	/10/2023	Version: 2 (Replaced 1)		
SECTION 14: T	RANSPORT INFORMATION ((continued)			
With rega	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			
	instruments:				

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

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CZ0961 - Isoamylase 13A, Escherichia coli

Date of compilation: 23/06/2020	Revised: 12/10/2023	Version: 2 (Replaced 1)
SECTION 16: OTHER INFORM	ATION ** (continued)	
COMMISSION REGULATION CLP Regulation (EC) No 127 · Hazard statements	(EU) 2020/878 2/2008 (SECTION 2, SECTION 2) (SECTION 2	ON 16):
Texts of the legislative p H315: Causes skin irritation H360D: May damage the ur H319: Causes serious eye i	nborn child.	tion 2:
	ohrases mentioned in sec	tion 3:
The phrases indicated do n individual components whi		; they are present merely for informative purposes and refer to the
CLP Regulation (EC) No		
Acute Tox. 4: H302 - Harm	ful if swallowed.	
Eye Dam. 1: H318 - Causes		
Repr. 1B: H360D - May dan		
	es severe skin burns and eye	e damage.
Advice related to trainin	•	viele for staff using this and ust and to fasilitate their commuch ancien and
	data sheet, as well as the	risks for staff using this product and to facilitate their comprehension and label on the product.
Principal bibliographical	sources:	
http://echa.europa.eu		
http://eur-lex.europa.eu		
Abbreviations and acron	-	
		al carriage of dangerous goods by road
IMDG: International maritin		
IATA: International Air Tra ICAO: International Civil Av	•	
COD: Chemical Oxygen De		
BOD5: 5day biochemical ox	vgen demand	
BCF: Bioconcentration factor		
LD50: Lethal Dose 50		
LC50: Lethal Concentration		
EC50: Effective concentration		
LogPOW: Octanolwater par		
Koc: Partition coefficient of UFI: unique formula identif IARC: International Agency	⁻ organic carbon fier	

** 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.