

LIPASE_R1

Creation date	27th October 2015	Version	4.0
Revision date	20th February 2024		

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1. Product identifier**

Substance / mixture	LIPASE_R1
Number	mixture
Other mixture names	XSYS0081
LIP 110	

1.2. Relevant identified uses of the substance or mixture and uses advised against**Mixture's intended use**

Diagnostic reagent for quantitative in vitro determination of Lipase in human serum and plasma.

Main intended use

PC-MED-OTH	Other medical devices
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Secondary uses

PC-TEC-19	Reagents and laboratory chemicals
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The use descriptors

PC 21	Laboratory chemicals
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Mixture uses advised against

not available

1.3. Details of the supplier of the safety data sheet**Manufacturer**

Name or trade name	Erba Lachema s.r.o.
Address	Karásek 2219/1d , Brno, 62100
	Czech Republic
Identification number (CRN)	26918846
VAT Reg No	CZ26918846
Phone	+420 517 077 111
E-mail	msds@erba.com
Web address	www.erbalachema.com

Competent person responsible for the safety data sheet

Name	Erba Lachema s.r.o.
E-mail	msds@erba.com

1.4. Emergency telephone number

European emergency number: 112 112

SECTION 2: Hazards identification**2.1. Classification of the substance or mixture****Classification of the mixture in accordance with Regulation (EC) No 1272/2008**

The mixture is not classified as dangerous according to Regulation (EC) No 1272/2008.

2.2. Label elements

none

2.3. Other hazards

The mixture does not contain substances with endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605. Mixture does not contain any substance meet the criteria for PBT or vPvB in accordance with Annex XIII of Regulation (EC) No. 1907/2006 (REACH) as amended.

LIPASE_R1

Creation date 27th October 2015
Revision date 20th February 2024 Version 4.0

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Chemical characterization

Mixture of substances and additives specified below.

Mixture contains these hazardous substances and substances with the highest permissible concentration in the working environment

Identification numbers	Substance name	Content in % weight	Classification according to Regulation (EC) No 1272/2008	Note
Index: 011-002-00-6 CAS: 1310-73-2 EC: 215-185-5 Registration number: 01-2119457892-27-0000	sodium hydroxide	<0,5	Met. Corr. 1, H290 Skin Corr. 1A, H314 Eye Dam. 1, H318 Specific concentration limit: Skin Corr. 1B, H314: $2 \% \leq C < 5 \%$ Skin Corr. 1A, H314: $C \geq 5 \%$ Eye Irrit. 2, H319: $0.5 \% \leq C < 2 \%$ Skin Irrit. 2, H315: $0.5 \% \leq C < 2 \%$	1
Index: 011-004-00-7 CAS: 26628-22-8 EC: 247-852-1	sodium azide	<0,1	Acute Tox. 2, H300 Aquatic Acute 1, H400 (M=1) Aquatic Chronic 1, H410 (M=1) EUH032	1

Notes

1 A substance for which exposure limits are set.

Full text of all classifications and hazard statements is given in the section 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

Take care of your own safety. If any health problems are manifested or if in doubt, inform a doctor and show him information from this safety data sheet.

If inhaled

Terminate the exposure immediately; move the affected person to fresh air. Get medical attention if irritation or other symptoms persist.

If on skin

Remove contaminated clothes. After contact with skin, wash with soap and water. If symptoms remain, obtain medical attention.

If in eyes

Rinse eyes immediately with a flow of running water, open the eyelids (also using force if needed); remove contact lenses immediately if worn by the affected person.

If swallowed

Rinse out the mouth with clean water. DO NOT INDUCE VOMITING! In the event of issues, find medical help.

4.2. Most important symptoms and effects, both acute and delayed

If inhaled

May cause respiratory irritation.

If on skin

May cause skin irritation.

If in eyes

May cause severe irritation.

If swallowed

May be harmful.

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

Symptomatic treatment.

LIPASE_R1

Creation date	27th October 2015	Version	4.0
Revision date	20th February 2024		

SECTION 5: Firefighting measures**5.1. Extinguishing media****Suitable extinguishing media**

Accommodate extinguishing components to the location of fire. Alcohol-resistant foam, carbon dioxide, powder, water spray jet, water mist.

Unsuitable extinguishing media

not available

5.2. Special hazards arising from the substance or mixture

Thermal decomposition or combustion may generate toxic and hazardous fumes of CO_x, PO_x, NO_x and Na₂O.

5.3. Advice for firefighters

Self-Contained Breathing Apparatus (SCBA) with chemical resistant gloves. Use a self-contained breathing apparatus and full-body protective clothing.

SECTION 6: Accidental release measures**6.1. Personal precautions, protective equipment and emergency procedures**

Follow the instructions in the Sections 7 and 8. Remove the ignition and heat sources, provide sufficient ventilation and evacuate the area. Respiratory protection: not required. Where risk assessment shows air-purifying respirators are appropriate, use masks with approved filter. Suitable protective clothing, rubber or polythene gloves, rubber shoes, safety glasses.

6.2. Environmental precautions

Prevent contamination of the soil and entering surface or ground water.

6.3. Methods and material for containment and cleaning up

After removal of the product, wash the contaminated site with plenty of water.

6.4. Reference to other sections

See the Section 7, 8 and 13.

SECTION 7: Handling and storage**7.1. Precautions for safe handling**

Prevent formation of gases and vapours in concentrations exceeding the occupational exposure limits. Ensure a sufficient ventilation. Use personal protective equipment as per Section 8. Observe valid legal regulations on safety and health protection.

7.2. Conditions for safe storage, including any incompatibilities

Store in a well-ventilated place. Keep containers tightly closed and labelled with the name of the product. Avoid environmental release. Keep away from food and drinks. Keep away from contamination with heavy metals. Sodium azide has been reported to form lead or copper azide in laboratory plumbing which may explode on percussion.

Storage temperature

min 2 °C, max 8 °C

7.3. Specific end use(s)

The kit is designed for in vitro diagnostic devices.

SECTION 8: Exposure controls/personal protection**8.1. Control parameters**

The mixture contains substances for which occupational exposure limits are set.

Czech Republic**Government Regulation 330/2023 Coll.**

Substance name (component)	Type	Value	Note
sodium hydroxide (CAS: 1310-73-2)	PEL	1 mg/m ³	irritating to mucous membranes (eyes, respiratory system) and skin
	NPK-P	2 mg/m ³	
sodium azide (CAS: 26628-22-8)	PEL	0,1 mg/m ³	skin penetration is significantly involved during exposure, irritating to mucous membranes (eyes, respiratory system) and skin

LIPASE_R1

Creation date	27th October 2015	Version	4.0
Revision date	20th February 2024		

Czech Republic

Government Regulation 330/2023 Coll.

Substance name (component)	Type	Value	Note
sodium azide (CAS: 26628-22-8)	NPK-P	0,3 mg/m ³	skin penetration is significantly involved during exposure, irritating to mucous membranes (eyes, respiratory system) and skin

European Union

Commission Directive 2000/39/EC

Substance name (component)	Type	Value	Note
sodium azide (CAS: 26628-22-8)	OEL 8 hours	0,1 mg/m ³	Skin
	OEL 15 minutes	0,3 mg/m ³	

8.2. Exposure controls

Do not eat, drink and smoke during work. Wash your hands thoroughly with water and soap after work and before breaks for a meal and rest.

Eye/face protection

Safety goggles are recommended.

Skin protection

When handling in long-term or repeatedly, use protective gloves. Handle with rubber or polyethylene gloves. Gloves must be inspected prior to use. Use proper gloves removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and Good Laboratory Practices

Respiratory protection

Under good ventilation/ exhaust at the workplace, the use of these products should not require respiratory protection.

Thermal hazard

Not available.

Environmental exposure controls

Observe usual measures for protection of the environment, see Section 6.2.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	liquid
Colour	colourless
Odour	without fragrance
Melting point/freezing point	0 °C
Boiling point or initial boiling point and boiling range	>90 °C
Flammability	The product is non-flammable.
Lower and upper explosion limit	data not available
Flash point	data not available
Auto-ignition temperature	data not available
Decomposition temperature	data not available
pH	8 (undiluted at 20 °C)
Kinematic viscosity	data not available
Solubility in water	data not available
Solubility in fats	data not available
Partition coefficient n-octanol/water (log value)	data not available
Vapour pressure	data not available
Density and/or relative density	
Density	1.00682 g/cm ³
Relative vapour density	data not available

LIPASE_R1

Creation date	27th October 2015	Version	4.0
Revision date	20th February 2024		

Particle characteristics	data not available
Form	Clear colourless liquid
9.2. Other information	
Evaporation rate	data not available
Oxidising properties	The product has no oxidizing properties.
Explosive properties	The product does not have explosive properties.

SECTION 10: Stability and reactivity**10.1. Reactivity**

not available

10.2. Chemical stability

The product is stable until the expiration date shown on the box and on the labels when stored at 2-8°C.

10.3. Possibility of hazardous reactions

Under the normal conditions of storage and usage, hazardous reactions are not expected.

10.4. Conditions to avoid

Keep out from heat and light.

10.5. Incompatible materials

Strong oxidizing agents, acids, heavy metals and their salts. Sodium azide reacts with many heavy metals to form explosive compounds. Sodium azide has been reported to form lead or copper azide in laboratory plumbing which may explode on percussions. Sodium azide reacts vigorously with heated water. Sodium azide can develop toxic gas in contact with strong acids.

10.6. Hazardous decomposition products

Thermal decomposition or combustion may include toxic and hazardous fumes.

SECTION 11: Toxicological information**11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008**

Inhalation of solvent vapors above values exceeding exposure limits for working environment may result in acute inhalation poisoning, depending on the level of concentration and exposure time. No toxicological data is available for the mixture.

Acute toxicity

Based on the available data, the criteria for classification of the mixture are not met.

LIPASE_R1						
Route of exposure	Parameter	Value	Exposure time	Species	Sex	Value determination
Oral	ATE	27000 mg/kg				Calculation of value

sodium azide						
Route of exposure	Parameter	Value	Exposure time	Species	Sex	Value determination
Oral	LD ₅₀	27 mg/kg bw				
Inhalation	LC ₅₀	54 mg/m ³	4 hours	Rat		

sodium hydroxide						
Route of exposure	Parameter	Value	Exposure time	Species	Sex	Value determination
Oral	LD ₅₀	325 mg/kg		Rat		
Dermal	LD ₅₀	1350 mg/kg		Rabbit		
Oral	LD ₅₀	500 mg/kg		Rabbit		
Dermal	LD ₅₀	40 mg/kg		Mouse		

Skin corrosion/irritation

No data are available for either the mixture or the components. Based on the available data, the criteria for classification of the mixture are not met.

LIPASE_R1

Creation date	27th October 2015		
Revision date	20th February 2024	Version	4.0

Serious eye damage/irritation

No data are available for either the mixture or the components. Based on the available data, the criteria for classification of the mixture are not met.

Respiratory or skin sensitisation

No data are available for either the mixture or the components. Based on the available data, the criteria for classification of the mixture are not met.

Germ cell mutagenicity

No data are available for either the mixture or the components. Based on the available data, the criteria for classification of the mixture are not met.

Carcinogenicity

No data are available for either the mixture or the components. Based on the available data, the criteria for classification of the mixture are not met.

Reproductive toxicity

No data are available for either the mixture or the components. Based on the available data, the criteria for classification of the mixture are not met.

Toxicity for specific target organ - single exposure

No data are available for either the mixture or the components. Based on the available data, the criteria for classification of the mixture are not met.

Toxicity for specific target organ - repeated exposure

No data are available for either the mixture or the components. Based on the available data, the criteria for classification of the mixture are not met.

Aspiration hazard

No data are available for either the mixture or the components. Based on the available data, the criteria for classification of the mixture are not met.

11.2. Information on other hazards

The mixture does not contain substances with endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605.

SECTION 12: Ecological information**12.1. Toxicity**

Data for the mixture are not available. Based on the available data, the criteria for classification of the mixture are not met.

Acute toxicity

sodium azide				
Parameter	Value	Exposure time	Species	Environment
LC ₅₀	680 µg/l		Fish	Fresh water
EC ₅₀ /LC ₅₀	400 µg/l		Invertebrates	Fresh water
EC ₅₀ /LC ₅₀	150 µg/l		Invertebrates	Salt water
EC ₅₀ /LC ₅₀	348 µg/l		Algae	Fresh water
EC ₅₀ /LC ₅₀	5.6 mg/l		Microorganisms	
NOEC	30 µg/l		Microorganisms	

LIPASE_R1

Creation date 27th October 2015
 Revision date 20th February 2024 Version 4.0

sodium hydroxide				
Parameter	Value	Exposure time	Species	Environment
EC ₅₀	76 mg/l	24 hours	Daphnia (Daphnia magna)	
EC ₅₀	145 mg/l	24 hours	Fish (Poecilia reticulata)	
EC ₅₀	40.4 mg/l	48 hours	Daphnia (Daphnia magna)	
LC ₅₀	160 mg/l	24 hours	Fish (Carassius auratus)	

12.2. Persistence and degradability

Sodium Hydroxide:

Sodium hydroxide is highly soluble in water and dissociates into ions and sodium hydroxide with the effect of increase the pH and alkalinity. Na⁺ ions and OH⁻ persist permanently in the environment in balance between various forms (complexes and precipitates).

Sodium Azide:

Sodium azide normally has a very short half life in plants. It is degraded by two paths - the azide ion can be oxidized by natural plant oxidizing agents such as nitrites, or hydrazoic acid could be formed by ion exchange and this can react with organic acids to form azides of these acids, which through some reactions release N₂ and CO₂.

12.3. Bioaccumulative potential

Sodium Hydroxide:

Considering the great water solubility of sodium hydroxide a significant bioconcentration in organisms is not expected.

12.4. Mobility in soil

Sodium Hydroxide:

Sodium hydroxide is very soluble and mobile in water, where it is present in the form of sodium ion (Na⁺) and hydroxide ion (OH⁻). In the soil, its mobility is a function of percentage of liquid phase present and the ability to form hydroxides-complex, especially with metal ions present.

Sodium Azide:

Dissipation of azides in soil does not occur through microbial action, but a chemical process, accelerated by increased acidity and high temperatures.

12.5. Results of PBT and vPvB assessment

Product does not contain any substance meeting the criteria for PBT or vPvB in accordance with the Annex XIII of Regulation (EC) No 1907/2006 (REACH) as amended.

12.6. Endocrine disrupting properties

The mixture does not contain substances with endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605.

12.7. Other adverse effects

Sodium Hydroxide:

The effects of sodium hydroxide on organisms depend on the buffering capacity of the aquatic and terrestrial ecosystem.

Sodium Azide:

Very toxic to aquatic life with long lasting effects.

SECTION 13: Disposal considerations**13.1. Waste treatment methods**

Hazard of environmental contamination; dispose of the waste in accordance with the local and/or national regulations. Proceed in accordance with valid regulations on waste disposal. Any unused product and contaminated packaging should be put in labelled containers for waste collection and submitted for disposal to a person authorised for waste removal (a specialized company) that is entitled for such activity. Do not empty unused product in drainage systems. The product must not be disposed of with municipal waste. Empty containers may be used at waste incinerators to produce energy or deposited in a dump with appropriate classification. Perfectly cleaned containers can be submitted for recycling.

Waste management legislation

Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste, as amended. Decision 2000/532/EC establishing a list of wastes, as amended.

LIPASE_R1

Creation date	27th October 2015		
Revision date	20th February 2024	Version	4.0

SECTION 14: Transport information

- 14.1. UN number or ID number**
not subject to transport regulations
- 14.2. UN proper shipping name**
not relevant
- 14.3. Transport hazard class(es)**
not relevant
- 14.4. Packing group**
not relevant
- 14.5. Environmental hazards**
not relevant
- 14.6. Special precautions for user**
Reference in the Sections 4 to 8.
- 14.7. Maritime transport in bulk according to IMO instruments**
not relevant

SECTION 15: Regulatory information**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture**

Regulation (EC) No. 1907/2006 of the European Parliament and of the Council of 18th December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing the European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No. 793/93 and Commission Regulation (EC) No. 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, as amended. REGULATION (EC) No. 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL as amended. Regulation (EC) No. 1272/2008 of the European Parliament and of the Council of 16th December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No. 1907/2006, as amended. Commission Regulation (EU) 2020/878 of 18 June 2020 amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

15.2. Chemical safety assessment

not available

SECTION 16: Other information**A list of standard risk phrases used in the safety data sheet**

H290	May be corrosive to metals.
H300	Fatal if swallowed.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.

A list of additional standard phrases used in the safety data sheet

EUH032	Contact with acids liberates very toxic gas.
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Other important information about human health protection

The product must not be - unless specifically approved by the manufacturer/importer - used for purposes other than as per the Section 1. The user is responsible for adherence to all related health protection regulations.

Key to abbreviations and acronyms used in the safety data sheet

ADR	European agreement concerning the international carriage of dangerous goods by road
BCF	Bioconcentration Factor
CAS	Chemical Abstracts Service
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substance and mixtures
EC	Identification code for each substance listed in EINECS

LIPASE_R1

Creation date	27th October 2015	Version	4.0
Revision date	20th February 2024		

EC ₅₀	Concentration of a substance when it is affected 50% of the population
EINECS	European Inventory of Existing Commercial Chemical Substances
EmS	Emergency plan
EU	European Union
EuPCS	European Product Categorisation System
IATA	International Air Transport Association
IBC	International Code For The Construction And Equipment of Ships Carrying Dangerous Chemicals
ICAO	International Civil Aviation Organization
IMDG	International Maritime Dangerous Goods
IMO	International Maritime Organization
INCI	International Nomenclature of Cosmetic Ingredients
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
LC ₅₀	Lethal concentration of a substance in which it can be expected death of 50% of the population
LD ₅₀	Lethal dose of a substance in which it can be expected death of 50% of the population
log K _{ow}	Octanol-water partition coefficient
NOEC	No observed effect concentration
NPK	Maximum admissible concentration
OEL	Occupational Exposure Limits
PBT	Persistent, Bioaccumulative and Toxic
PEL	Permissible Exposure Limit
ppm	Parts per million
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RID	Agreement on the transport of dangerous goods by rail
UN	Four-figure identification number of the substance or article taken from the UN Model Regulations
UVCB	Substances of unknown or variable composition, complex reaction products or biological materials
VOC	Volatile organic compounds
vPvB	Very Persistent and very Bioaccumulative
Acute Tox.	Acute toxicity
Aquatic Acute	Hazardous to the aquatic environment
Aquatic Chronic	Hazardous to the aquatic environment (chronic)
Eye Dam.	Serious eye damage
Met. Corr.	Corrosive to metals
Skin Corr.	Skin corrosion

Training guidelines

Inform the personnel about the recommended ways of use, mandatory protective equipment, first aid and prohibited ways of handling the product.

Recommended restrictions of use

not available

Information about data sources used to compile the Safety Data Sheet

REGULATION (EC) No. 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL (REACH) as amended. REGULATION (EC) No. 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL as amended. Data from the manufacturer of the substance / mixture, if available - information from registration dossiers.

The changes (which information has been added, deleted or modified)

The version 4.0 replaces the SDS version from 31 March 2021. Changes were made in sections 2, 11, 12, 15 and 16.

Statement

LIPASE_R1

Creation date	27th October 2015		
Revision date	20th February 2024	Version	4.0

The safety data sheet provides information aimed at ensuring safety and health protection at work and environmental protection. The provided information corresponds to the current status of knowledge and experience and complies with valid legal regulations. The information should not be understood as guaranteeing the suitability and usability of the product for a particular application.