

ALKALINE PHOSPHATASE_R1

Creation date	20th May 2015	Version	5.0
Revision date	18th October 2024		

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

Substance / mixture	ALKALINE PHOSPHATASE_R1 mixture
Number	BLT00003, BLT00004, XSYS0002
Other mixture names	ALP AMP 150, ALP AMP 500, ALP 110

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

The reagent is a part of kit for in vitro quantitative determination of ALP in human serum or plasma.

Main intended use

PC-MED-OTH Other medical devices

Secondary uses

PC-TEC-19 Reagents and laboratory chemicals

The use descriptors

PC 21 Laboratory chemicals

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**Signal word**

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.

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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: 603-070-00-6 CAS: 124-68-5 EC: 204-709-8	2-amino-2-methylpropanol	<4	Skin Irrit. 2, H315 Eye Irrit. 2, H319 Aquatic Chronic 3, H412	
Index: 017-002-01-X CAS: 7647-01-0 EC: 231-595-7 Registration number: 01-2119484862-27-XXXX	Hydrochloric acid	<0.7	Met. Corr. 1, H290 Skin Corr. 1B, H314 STOT SE 3, H335 Specific concentration limit: STOT SE 3, H335: C ≥ 10 % Skin Corr. 1B, H314: C ≥ 25 % Skin Irrit. 2, H315: 10 % ≤ C < 25 % Eye Irrit. 2, H319: 10 % ≤ C < 25 %	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.

If on skin

Remove contaminated clothes. Wash with soap and water.

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. In the event of issues, find medical help.

4.2. Most important symptoms and effects, both acute and delayed**If inhaled**

Not expected.

If on skin

Mild irritation or drying of skin.

If in eyes

Mild irritation of eye conjunctiva.

If swallowed

Not expected.

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

Symptomatic treatment.

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

Accommodate extinguishing components to the location of fire.

Unsuitable extinguishing media

not available

5.2. Special hazards arising from the substance or mixture

In the event of fire, carbon monoxide, carbon dioxide and other toxic gases may arise. Inhalation of hazardous degradation (pyrolysis) products may cause serious health damage.

5.3. Advice for firefighters

No special advice.

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

Follow the instructions in the Sections 7 and 8.

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. 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 tightly closed containers in cold, dry and well ventilated areas designated for this purpose.

Storage temperature

min 2 °C, max 8 °C

7.3. Specific end use(s)

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
Hydrochloric acid (CAS: 7647-01-0)	PEL	8 mg/m ³
	PEL	5 ppm
	NPK-P	15 mg/m ³
	NPK-P	10 ppm

Notes

Irritating to mucous membranes (eyes, respiratory system) and skin.

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

Substance name (component)	Type	Value
sodium azide (CAS: 26628-22-8)	PEL	0,1 mg/m ³
	NPK-P	0,3 mg/m ³

Notes

Skin penetration is significantly involved during exposure.

Irritating to mucous membranes (eyes, respiratory system) and skin.

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European Union

Commission Directive 2000/39/EC

Substance name (component)	Type	Value
Hydrochloric acid (CAS: 7647-01-0)	OEL 8 hours	8 mg/m ³
	OEL 8 hours	5 ppm
	OEL 15 minutes	15 mg/m ³
	OEL 15 minutes	10 ppm

European Union

Commission Directive 2000/39/EC

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

Notes

Skin.

DNEL

Hydrochloric acid			
Workers / consumers	Route of exposure	Value	Effect
Workers	Inhalation	8.0 mg/m ³	Chronic effects systemic
Workers	Inhalation	15.0 mg/m ³	Acute effects systemic
Consumers	Inhalation	8.0 mg/m ³	Chronic effects systemic
Consumers	Inhalation	15.0 mg/m ³	Acute effects systemic

8.2. Exposure controls

Wash your hands thoroughly with water and soap after work and before breaks for a meal and rest.

Eye/face protection

It is not needed.

Skin protection

When handling in long-term or repeatedly, use protective gloves.

Respiratory protection

Not required.

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	data not available
Melting point/freezing point	data not available
Boiling point or initial boiling point and boiling range	data not available
Flammability	data not available
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	10.5 (undiluted)
Kinematic viscosity	data not available
Solubility in water	data not available

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Partition coefficient n-octanol/water (log value)	data not available
Vapour pressure	data not available
Density and/or relative density	data not available
Relative vapour density	data not available
Particle characteristics	data not available
Form	clear

9.2. Other information

not available

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

Under normal conditions of use and storage the mixture is stable.

10.2. Chemical stability

The product is stable under normal conditions.

10.3. Possibility of hazardous reactions

Unknown.

10.4. Conditions to avoid

The product is stable and no degradation occurs under normal use.

10.5. Incompatible materials

Unknown.

10.6. Hazardous decomposition products

Not developed under normal uses. Dangerous outcomes such as carbon monoxide and carbon dioxide are formed at high temperature and in fire.

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.

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

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.

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.

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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

Hydrochloric acid				
Parameter	Value	Exposure time	Species	Environment
LC ₅₀	20.5 mg/l	96 hours	Fish	Fresh water
EC ₅₀	0.73 mg/l	72 hours	Algae	Fresh water
NOEC	0.36 mg/l	72 hours	Algae	Fresh water
EC ₅₀	0.23 mg/l		Microorganisms	
EC ₅₀	0.45 mg/l	48 hours	Crustaceans	

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	

12.2. Persistence and degradability

Data for the components of the mixture are not available.

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Biodegradability**ALKALINE PHOSPHATASE_R1**

Parameter	Value	Exposure time	Environment	Result
				Easily biodegradable

12.3. Bioaccumulative potential

No data are available for either the mixture or the components.

12.4. Mobility in soil

No data are available for either the mixture or the components.

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

Not available.

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.

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

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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**

EUH032	Contact with acids liberates very toxic gas.
H290	May be corrosive to metals.
H300	Fatal if swallowed.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.

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

Acute Tox.	Acute toxicity
ADR	European agreement concerning the international carriage of dangerous goods by road
Aquatic Acute	Hazardous to the aquatic environment
Aquatic Chronic	Hazardous to the aquatic environment (chronic)
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
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
Eye Irrit.	Eye irritation
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

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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
Met. Corr.	Corrosive to metals
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
Skin Corr.	Skin corrosion
Skin Irrit.	Skin irritation
STOT SE	Specific target organ toxicity - single exposure
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

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

For in vitro diagnostic use only.

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 5.0 replaces the SDS version from Friday, 24 November 2023. Changes were made in sections 2 and 16.

Statement

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.