

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 |
| Number | mixture |
| Other mixture names | BLT00003, BLT00004, XSYS0002 |
| 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

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| 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.