

ERBA PROTIME_R1

| | | | |
|---------------|-------------------|---------|-----|
| Creation date | 29th October 2018 | | |
| Revision date | 22nd October 2024 | Version | 4.0 |

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

| | |
|------------------------------------|--------------------|
| Substance / mixture | ERBA PROTIME_R1 |
| Number | mixture |
| Other mixture names | EHL00001; EHL00002 |
| Erba Prottime 20; Erba Prottime 40 | |

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

Erba Prottime is intended for the determination of the prothrombin time (PT).

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

The product should not be used in ways other than those referred in Section 1.

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 classified as dangerous.

Aquatic Chronic 3, H412

Most serious adverse effects on human health and the environment

Harmful to aquatic life with long lasting effects.

2.2. Label elements**Hazard statements**

| | |
|------|----------------------------------------------------|
| H412 | Harmful to aquatic life with long lasting effects. |
|------|----------------------------------------------------|

Precautionary statements

| | |
|------|-----------------------------------|
| P273 | Avoid release to the environment. |
|------|-----------------------------------|

2.3. Other hazards

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. The mixture contains 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. Dust may form explosive mixture with air.

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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 |
|---------------------------------------------------------|-------------------------------------------|---------------------|-------------------------------------------------------------------------------------------------------------------------|---------|
| CAS: 137-40-6 EC: 205-290-4 | Sodium propionate | 1-5 | Acute Tox. 4, H312 | |
| CAS: 9002-93-1 EC: 618-344-0 | p-tertiary-Octylphenoxy polyethyl alcohol | <0.25 | Acute Tox. 4, H302 Skin Irrit. 2, H315 Eye Dam. 1, H318 Aquatic Acute 1, H400 (M=1) Aquatic Chronic 1, H410 | 2, 3, 4 |
| 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.
- 2 Substance of very high concern - SVHC.
- 3 Endocrine disruptor for the environment
- 4 The substance is included in Annex XIV of the REACH Regulation

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. Protect the person against growing cold. Provide medical treatment if irritation, dyspnoea or other symptoms persist.

If on skin

Remove contaminated clothes. Wash the affected area with plenty of water, lukewarm if possible. Soap, soap solution or shampoo should be used if there is no skin injury. Provide medical treatment if skin irritation persists.

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. Rinsing should continue at least for 10 minutes.

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

Not expected.

If in eyes

Not expected.

If swallowed

Not expected.

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

Symptomatic treatment. Upon contact with a doctor, make sure to have the label or this safety data sheet with you.

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

Extinguish with materials intended for the surrounding fire. Alcohol-resistant foam, carbon dioxide, powder, water spray jet, water mist.

Unsuitable extinguishing media

Water - full jet.

5.2. Special hazards arising from the substance or mixture

The product is not hazardous in the flammable sense. Produces fumes containing harmful gases (carbon monoxide and carbon dioxide) when burning.

5.3. Advice for firefighters

Self-Contained Breathing Apparatus (SCBA) with a chemical protection suit only where personal (close) contact is likely. Use a self-contained breathing apparatus and full-body protective clothing. Do not allow run-off of contaminated fire extinguishing material to enter drains or surface and ground water.

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

Use personal protective equipment for work. Follow the instructions in the Sections 7 and 8. Avoid inhalation and exposure to skin and eyes. Ensure good ventilation. Avoid dust formation.

6.2. Environmental precautions

Avoid release to drains, soil or watercourses. Notify rescue services for larger spillage.

6.3. Methods and material for containment and cleaning up

Carefully collect the material for combustion waste disposal, then wash the spillage area with water. Avoid stirring the material up so that it aerates.

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. Avoid release to the environment. Store this product separately from food items and keep it out of the reach of children and pets. Avoid spillage and contact with eyes and skin. Avoid handling in a manner which will raise dust. Wash your hands after using the product. Handle in premises which have modern ventilation standards.

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. The product should be stored in a manner which prevents hazards to health and the environment. Avoid exposure to humans and animals and do not discharge the product in a sensitive environment.

This product should be stored well out of reach of young children and kept safely apart from products intended for consumption. Store only in the original package.

Storage temperature

min 2 °C, max 8 °C

7.3. Specific end use(s)

not available

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 |
|--------------------------------|-------|-----------------------|
| 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 |
|--------------------------------|----------------|-----------------------|
| sodium azide (CAS: 26628-22-8) | OEL 8 hours | 0,1 mg/m ³ |
| | OEL 15 minutes | 0,3 mg/m ³ |

Notes

Skin.

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

Use protective glasses, safety goggles, or a visor.

Skin protection

Protective gloves are normally not needed due to the properties of this product, but may be necessary for other reasons, e.g. mechanical risks, temperature conditions or microbiological risks. Use suitable protective clothing.

Respiratory protection

If all workplace limits are observed and good ventilation is ensured, no special precautions necessary.

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 | solid (lyophilised powder) |
| Colour | off-white |
| Odour | scentless |
| Melting point/freezing point | data not available |
| Boiling point or initial boiling point and boiling range | data not available |
| 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 | data not available |
| Kinematic viscosity | data not available |
| Solubility in water | data not available |
| 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 | Powder |

9.2. Other information

| | |
|----------------------|-------------------------------------------------|
| 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

The product contains no substances which can lead to hazardous reactions at normal use.

10.2. Chemical stability

The product is stable at normal storage and handling conditions.

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10.3. Possibility of hazardous reactions

No hazardous reactions known.

10.4. Conditions to avoid

The product is stable and no degradation occurs under normal use. Protect against flames, sparks, overheating and against frost.

10.5. Incompatible materials

Protect against strong acids, bases and oxidizing agents.

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.

p-tertiary-Octylphenoxy polyethyl alcohol

| Route of exposure | Parameter | Value | Exposure time | Species | Sex |
|-------------------|------------------|------------|---------------|---------|-----|
| Oral | LD ₅₀ | 500 mg/kg | | Rat | |
| Dermal | LD ₅₀ | 8000 mg/kg | | Rabbit | |

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. Mild irritation may occur on prolonged or repeated exposure.

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.

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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**

Harmful to aquatic life with long lasting effects. Prevent release on land, in water and drains.

Acute toxicity**p-tertiary-Octylphenoxy polyethyl alcohol**

| Parameter | Value | Exposure time | Species | Environment |
|------------------|----------|---------------|----------------------------|-------------|
| LC ₅₀ | 8.9 mg/l | 96 hours | Fish (Pimephales promelas) | |
| EC ₅₀ | 26 mg/l | 48 hours | Daphnia (Daphnia magna) | |

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

No information about persistence or degradability exists but there is no reason to suppose that the product is persistent.

12.3. Bioaccumulative potential

No information exists on bioaccumulation, but there is no cause for concern in respect of this.

12.4. Mobility in soil

No information about mobility in the nature exists but there is no reason to suppose the product to be ecologically harmful because of this.

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 contains 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.

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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.

Waste type code

16 05 06* laboratory chemicals, consisting of or containing hazardous substances, including mixtures of laboratory chemicals

Packaging waste type code

15 01 10* packaging containing residues of or contaminated by hazardous substances

(*) - Hazardous waste according to Directive 2008/98/EC on hazardous waste

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**

| | |
|--------|----------------------------------------------|
| EUH032 | Contact with acids liberates very toxic gas. |
| H300 | Fatal if swallowed. |

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| | |
|------|-------------------------------------------------------|
| H302 | Harmful if swallowed. |
| H312 | Harmful in contact with skin. |
| H315 | Causes skin irritation. |
| H318 | Causes serious eye damage. |
| 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. |

Guidelines for safe handling used in the safety data sheet

P273 Avoid release to the environment.

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 Dam. | Serious eye damage |
| 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 |
| Skin Irrit. | Skin irritation |
| 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 |

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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

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 Thursday, 9 November 2023. Changes were made in sections 2, 12 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.