

Erba Protime LS 100

Creation date	08th October 2021		
Revision date	23rd October 2023	Version	2.0

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

Substance / mixture	Erba Protime LS 100
Number	mixture
UFI	EHL00047
Other mixture names	YEJV-XWDV-CJ58-VEY2
	Erba Protime LS 100

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

Erba Protime LS is a liquid ready to use rabbit brain thromboplastin 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

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 classified as dangerous.

Skin Irrit. 2, H315
Skin Sens. 1A, H317
Eye Irrit. 2, H319
Aquatic Chronic 3, H412

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

Most serious adverse effects on human health and the environment

May cause an allergic skin reaction. Causes skin irritation. Causes serious eye irritation. Harmful to aquatic life with long lasting effects.

Erba Protime LS 100

Creation date	08th October 2021	Version	2.0
Revision date	23rd October 2023		

2.2. Label elements

Hazard pictogram



Signal word
Warning

Hazardous substances

2-methylisothiazol-3(2H)-one

Hazard statements

H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H412	Harmful to aquatic life with long lasting effects.

Precautionary statements

P264	Wash hands and exposed parts of the body thoroughly after handling.
P280	Wear protective gloves/protective clothing/eye protection.
P314	Get medical advice/attention if you feel unwell.

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.

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: 613-326-00-9 CAS: 2682-20-4 EC: 220-239-6	2-methylisothiazol-3(2H)-one	<1	Acute Tox. 3, H301, H311 Skin Corr. 1B, H314 Skin Sens. 1A, H317 Eye Dam. 1, H318 Acute Tox. 2, H330 Aquatic Acute 1, H400 (M=10) Aquatic Chronic 1, H410 (M=1) EUH071 Specific concentration limit: Skin Sens. 1A, H317: C ≥ 0.0015 %	
CAS: 9002-93-1 EC: 618-344-0	2-[4-(2,4,4-trimethylpentan-2-yl)phenoxy] ethanol	<1	Acute Tox. 4, H302 Skin Irrit. 2, H315 Eye Dam. 1, H318 Aquatic Acute 1, H400 (M=10) Aquatic Chronic 1, H410	1, 2

Notes

- 1 Substance of very high concern - SVHC.
- 2 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.

Erba Protime LS 100

Creation date	08th October 2021		
Revision date	23rd October 2023	Version	2.0

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. Provide medical treatment, specialized if possible.

If swallowed

Rinse out the mouth with water and provide 2-5 dL of water. Provide medical treatment if the person has any health problems.

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

Exposure may cause coughing or wheezing.

If on skin

May cause an allergic skin reaction. There may be irritation and redness at the site of contact.

If in eyes

There may be irritation and redness. The eyes may water profusely.

If swallowed

Irritation, nausea. There may be soreness and redness of the mouth and throat.

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

Symptomatic treatment.

More information

Delayed effects can be expected after long-term exposure.

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

Alcohol-resistant foam, carbon dioxide, powder, water spray jet, water mist. Suitable extinguishing media for the surrounding fire should be used. Use water spray to cool containers.

Unsuitable extinguishing media

Water - full jet.

5.2. Special hazards arising from the substance or mixture

In combustion emits toxic fumes.

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. Prevent contact with skin and eyes. Turn leaking containers leak-side up to prevent the escape of liquid.

6.2. Environmental precautions

Prevent contamination of the soil and entering surface or ground water. Contain the spillage using bunding.

Erba Protime LS 100

Creation date	08th October 2021		
Revision date	23rd October 2023	Version	2.0

6.3. Methods and material for containment and cleaning up

Spilled product should be covered with suitable (non-flammable) absorbing material (sand, diatomaceous earth, earth and other suitable absorption materials); to be contained in well closed containers and removed as per the Section 13. In the event of leakage of the substantial amount of the product, inform fire brigade and other competent bodies. After removal of the product, wash the contaminated site with plenty of water. Do not use solvents.

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 contact with skin and eyes. Contaminated work clothing should not be allowed out of the workplace. Wash hands and exposed parts of the body thoroughly after handling. Use personal protective equipment as per Section 8. Observe valid legal regulations on safety and health protection. Avoid release to the environment.

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. Must only be kept in original packaging.

Storage temperature min 2 °C, max 8 °C

7.3. Specific end use(s)

The reagent of the kit is designed for in vitro diagnostic use.

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

The mixture contains substances for which occupational exposure limits are set. The mixture contains no substances for which occupational exposure limits are set.

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

Protective goggles. Ensure eye bath is to hand.

Skin protection

Hand protection: Protective gloves resistant to the product. When choosing appropriate thickness, material and permeability of the gloves, observe recommendations of their particular manufacturer. Observe other recommendations of the manufacturer. Other protection: protective workwear. Contaminated skin should be washed thoroughly.

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	liquid
Colour	brown, Beige
Odour	odourless
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	data not available

Erba Protime LS 100

Creation date	08th October 2021	Version	2.0
Revision date	23rd October 2023		

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

9.2. Other information

not available

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

Stable under recommended transport or storage conditions.

10.2. Chemical stability

The product is stable under normal conditions.

10.3. Possibility of hazardous reactions

Hazardous reactions will not occur under normal transport or storage conditions. Decomposition may occur on exposure to conditions or materials listed below.

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.

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

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.

Erba Protime LS 100						
Route of exposure	Parameter	Value	Exposure time	Species	Sex	Value determination
Oral	ATE	8418 mg/kg				Calculation of value
Dermal	ATE	30300 mg/kg				Calculation of value
Inhalation (vapor)	ATE	50.51 mg/l				Calculation of value

2-[4-(2,4,4-trimethylpentan-2-yl)phenoxy]ethanol

Route of exposure	Parameter	Value	Exposure time	Species	Sex	Value determination
Dermal	LD ₅₀	3000 mg/kg		Rabbit		

Skin corrosion/irritation

Causes skin irritation. Data for the components of the mixture are not available.

Serious eye damage/irritation

Causes serious eye irritation. Data for the components of the mixture are not available.

Erba Protime LS 100

Creation date	08th October 2021		
Revision date	23rd October 2023	Version	2.0

Respiratory or skin sensitisation

May cause an allergic skin reaction. Data for the components of the mixture are not available.

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**

Harmful to aquatic life with long lasting effects.

Acute toxicity

2-[4-(2,4,4-trimethylpentan-2-yl)phenoxy]ethanol				
Parameter	Value	Exposure time	Species	Environment
LC ₅₀	4 mg/l	96 hours	Fish (Pimephales promelas)	
EC ₅₀	18 mg/l	48 hours	Daphnia (Daphnia magna)	

12.2. Persistence and degradability

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

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 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.

Erba Protime LS 100

Creation date	08th October 2021		
Revision date	23rd October 2023	Version	2.0

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.

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

Erba Protime LS 100

Creation date	08th October 2021	Version	2.0
Revision date	23rd October 2023		

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

H301	Toxic if swallowed.
H302	Harmful if swallowed.
H311	Toxic in contact with skin.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H330	Fatal if inhaled.
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

P264	Wash hands and exposed parts of the body thoroughly after handling.
P280	Wear protective gloves/protective clothing/eye protection.
P314	Get medical advice/attention if you feel unwell.

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

EUH071	Corrosive to the respiratory tract.
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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
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 Kow	Octanol-water partition coefficient
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

Erba Protime LS 100

Creation date	08th October 2021	Version	2.0
Revision date	23rd October 2023		

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
Skin Corr.	Skin corrosion
Skin Sens.	Skin sensitization

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 2.0 replaces the SDS version from 08 October 2021. Changes were made in sections 1, 2, 11, 15 and 16.

More information

Classification procedure - calculation method.

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.