

Erba Actime 50

Creation date	02nd October 2017		
Revision date	10th November 2023	Version	3.0

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

Substance / mixture	Erba Actime 50
Number	mixture
Other mixture names	EHL00004
Erba Actime	

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

Erba Actime is intended for the determination of the activated partial thromboplastin time (APTT) and related coagulation using phospholipidic extract and a near-colloidal particle activator.

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.

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

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.

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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: 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 symptoms persist seek medical advice.

If on skin

Remove contaminated clothes. Normal washing of the skin is considered sufficient; If nevertheless symptoms do occur, contact a physician.

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 irritation persists call a doctor.

If swallowed

Rinse nose, mouth and throat with 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.

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

Accommodate extinguishing components to the location of fire. Extinguish with water mist, powder, carbon dioxide or alcoholresistant foam.

Unsuitable extinguishing media

Not known.

5.2. Special hazards arising from the substance or mixture

In case of fire, substances hazardous to health, or substances harmful in other respects, may be dispersed.

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.

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

Follow the instructions in the Sections 7 and 8. Avoid inhalation and exposure to skin and eyes. Ensure good ventilation. Observe the principles of work safety in chemical laboratories.

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

Small spills can be wiped up with a cloth or similar. Then flush the spill site with water. Larger spills should first be covered with sand or earth and then be collected. Collected material should be disposed according to Section 13.

6.4. Reference to other sections

See the Section 7, 8 and 13.

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

Use personal protective equipment as per Section 8. Observe valid legal regulations on safety and health protection. Store this product separately from food items and keep it out of the reach of children and pets. Avoid spillage, inhalation and contact with eyes and skin. Do not eat, drink or smoke in premises where this product is handled. Wash your hands after using the product. Handle in premises which have modern ventilation standards. Remove contaminated clothing. Wash contaminated clothing before reuse.

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. This product should be stored well out of reach of young children and kept safely apart from products intended for consumption. 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. Always use sealed and visibly labeled packages.

Storage temperature

min 15 °C, max 25 °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 195/2021 Coll.**

Substance name (component)	Type	Value	Conversion for ppm	Note
sodium azide (CAS: 26628-22-8)	PEL	0,1 mg/m ³	0,370	skin penetration is significantly involved during exposure, irritating to mucous membranes (eyes, respiratory system) and skin
	NPK-P	0,3 mg/m ³	0,370	

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	

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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. Handle in premises which have modern ventilation standards.

Eye/face protection

It is not needed. Eye protection should be worn if there is any danger of direct exposure or splashing.

Skin protection

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

Respiratory protection

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

Thermal hazard

Not available.

Environmental exposure controls

Work with the product should take place in such a way that the product does not get into drains, waterways, soil and air.

SECTION 9: Physical and chemical properties**9.1. Information on basic physical and chemical properties**

Physical state	liquid
Colour	pink
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	not applicable
Auto-ignition temperature	data not available
Decomposition temperature	data not available
pH	5-8 (undiluted)
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	data not available
Relative vapour density	data not available
Particle characteristics	data not available

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**

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.

10.3. Possibility of hazardous reactions

No hazardous reactions known during normal use.

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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.

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Route of exposure	Parameter	Value	Exposure time	Species	Sex	Value determination
Oral	ATE	135000 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		

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.

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.

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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	

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 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.

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Waste type code

16 05 09 discarded chemicals other than those mentioned in 16 05 06, 16 05 07 or 16 05 08

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).

National regulations (Germany)

WGK Water hazard class: nwg - non-hazardous to water

15.2. Chemical safety assessment

not available

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

H300	Fatal if swallowed.
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

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EC	Identification code for each substance listed in EINECS
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
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)

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 3.0 replaces the SDS version from 01 September 2021. Changes were made in sections 1, 2, 11, 15 and 16.

More information

Classification procedure - calculation method.

Statement

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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.