

Erba LA2 Confirm

Creation date 26. February 2016
Revision date 20. August 2018 Version 1.1

SECTION 1: Identification of the substance/mixture and of the company/undertaking

- 1.1. Product identifier**
Substance / mixture Erba LA2 Confirm
Number EHL00038
- 1.2. Relevant identified uses of the substance or mixture and uses advised against**
mixture's intended use Erba LA2 Confirm is intended for the quantitative determination of LA (Lupus Anticoagulants) in human plasma.

The use descriptors

PC 21 Laboratory chemicals

Disapproved uses of mixture 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 (ID) 26918846
VAT Reg No CZ36918846
Phone +420 517 077 111
E-mail msds@erbamannheim.com
Web address www.erbalachema.com

Competent person responsible for the safety data sheet

Name Erba Lachema s.r.o.
E-mail msds@erbamannheim.com

1.4. Emergency telephone number

Poisoning information centre, Na Bojišti 1, Praha, Czech Republic, Tel.: non-stop +420 224 919 293 or +420 224 915 402, Information on health risks only - acute poisoning of humans and animals.

SECTION 2: Hazards identification**2.1. Substance or mixture classification****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

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.
CAS: 9002-93-1	Triton X-100	<10	Acute Tox. 4, H302 Eye Irrit. 2, H319 Aquatic Chronic 2, H411	1

Notes

1 Substance of very high concern - SVHC.

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

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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.

Inhalation

Terminate the exposure immediately; move the affected person to fresh air.

Skin contact

Remove contaminated clothes.

Eye contact

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.

Ingestion

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**Inhalation**

Not expected.

Skin contact

Not expected.

Eye contact

Not expected.

Ingestion

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.

Unsuitable extinguishing media

not available

5.2. Special hazards arising from the substance or mixture

In case of fire may liberate toxic fumes.

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.

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

Place the product mechanically in an appropriate manner. Dispose of the collected material according to the instructions in the section 13.

6.4. Reference to other sections

See the Section 7, 8 and 13.

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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.

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)

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

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

none

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

It is not needed.

Skin protection

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

Respiratory protection

It is not needed.

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****Appearance**

Physical state

solid at 20°C

color

white

Odour

odourless

Odour threshold

data not available

pH

data not available

Melting point/freezing point

data not available

Initial boiling point and boiling range

data not available

Flash point

data not available

Evaporation rate

data not available

Flammability (solid, gas)

data not available

Upper/lower flammability or explosive limits

flammability limits

data not available

explosive limits

data not available

Vapour pressure

data not available

Vapour density

data not available

Relative density

data not available

Solubility(ies)

solubility in water

data not available

solubility in fats

data not available

Partition coefficient: n-octanol/water

data not available

Auto-ignition temperature

data not available

Decomposition temperature

data not available

Viscosity

data not available

Explosive properties

data not available

Oxidising properties

data not available

9.2. Other information

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Density	data not available		
ignition temperature	data not available		

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

Data not available.

10.2. Chemical stability

The product is stable under normal conditions.

10.3. Possibility of hazardous reactions

Unknown.

10.4. Conditions to avoid

Protect against heating.

10.5. Incompatible materials

Protect against strong acids and oxidizing agents.

10.6. Hazardous decomposition products

No data available.

SECTION 11: Toxicological information**11.1. Information on toxicological effects**

No toxicological data is available for the mixture.

Acute toxicity

Based on available data the classification criteria are not met.

Triton X-100

Route of exposure	Parameter	Value	Time of exposure	Species	Sex
Dermal	LD ₅₀	8000 mg/kg		Rabbit	
Oral	LD ₅₀	1800 mg/kg		Rat	

Skin corrosion/irritation

Based on available data the classification criteria are not met.

Serious eye damage/irritation

Based on available data the classification criteria are not met.

Respiratory or skin sensitisation

Based on available data the classification criteria are not met.

Germ cell mutagenicity

Based on available data the classification criteria are not met.

Carcinogenicity

Based on available data the classification criteria are not met.

Reproductive toxicity

Based on available data the classification criteria are not met.

Toxicity for specific target organ - single exposure

Based on available data the classification criteria are not met.

Toxicity for specific target organ - repeated exposure

Based on available data the classification criteria are not met.

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Aspiration hazard

Based on available data the classification criteria are not met.

SECTION 12: Ecological information**12.1. Toxicity****Acute toxicity**

The mixture is not classified as toxic to environment.

Triton X-100

Parameter	Value	Time of exposure	Species	Environment
EC ₅₀	26 mg/l	48 hour	Daphnia (Daphnia magna)	
LC ₅₀	8.9 mg/l	96 hour	Fishes (Pimephales promelas)	

12.2. Persistence and degradability

Data not available.

12.3. Bioaccumulative potential

Not available.

12.4. Mobility in soil

Not available.

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. 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.

Legislation of waste

Council Directive 75/442/EEC on waste, as amended. Decree No. 383/2001 Coll., on details regarding waste handling as amended. Decree No. 93/2016 Coll., (waste catalogue) as amended. Decision 2000/532/EC establishing a list of wastes, as amended.

SECTION 14: Transport information**14.1. UN number**

Not subject to ADR.

14.2. UN proper shipping name

not available

14.3. Transport hazard class(es)

not available

14.4. Packing group

not available

14.5. Environmental hazards

not available

14.6. Special precautions for user

Reference in the Sections 4 to 8.

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14.7. Transport in bulk according to Annex II of Marpol and the IBC Code
not available

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 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. The Act No. 350/2011 Coll., on Chemical Substances and Chemical Preparations as amended (the Chemical Act). Decree No. 432/2003 Coll., laying down conditions for assigning categories to individual jobs, limit values of indices from biological exposure tests, conditions for the sampling of biological materials for biological exposure and the particulars of the reports on work with asbestos and biological agents as amended.

15.2. Chemical safety assessment

Assessment was not carried out.

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

H302	Harmful if swallowed.
H319	Causes serious eye irritation.
H411	Toxic 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

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
DNEL	Derived no-effect level
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
IATA	International Air Transport Association
IBC	International Code For The Construction And Equipment of Ships Carrying Dangerous Chemicals
IC ₅₀	Concentration causing 50% blockade
ICAO	International Civil Aviation Organization
IMDG	International Maritime Dangerous Goods
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
LOAEC	Lowest observed adverse effect concentration
LOAEL	Lowest observed adverse effect level
log K _{ow}	Octanol-water partition coefficient
MARPOL	International Convention for the Prevention of Pollution From Ships
NOAEC	No observed adverse effect concentration
NOAEL	No observed adverse effect level

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NOEC	No observed effect concentration
NOEL	No observed effect level
OEL	Occupational Exposure Limits
PBT	Persistent, Bioaccumulative and Toxic
PNEC	Predicted no-effect concentration
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 Chronic	Hazardous to the aquatic environment
Eye Irrit.	Eye irritation

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

This compound is designed for professional use. It should not be used for purposes other than those described in Section 1.2.

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. The Act No. 350/2011 Coll., on Chemical Substances and Chemical Preparations 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)

1.1 /20.8.2018/ Transfer to SBL Core

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.