

Erba H7100 Lyse2

Creation date	02nd May 2024	Version	1.0
Revision date			

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

- 1.1. Product identifier**
 Substance / mixture Erba H7100 Lyse2 mixture
 Number HEM0048, HEM0049, HEM0050, HEM0067
 Other mixture names
 Erba H7100 Lyse 2 (500 mL), Erba H7100 Lyse 2 (1000 mL), Erba H7100 Lyse 2 (2000 mL),
 Erba H7100 Lyse 2 (4000 mL)

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

Erba H7100 Lyse2 is an in vitro diagnostic reagent used for quantitative 5-part differentiation of white blood cells on automated haematology analysers H7100. It is designed to report on the haematological status of patient samples, supporting the monitoring and diagnosis of pathological conditions. For professional use in clinical laboratory only.

Main intended use

PC-MED-OTH Other medical devices

Secondary uses

PC-TEC-19 Reagents and 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

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**

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: 1119-94-4 EC: 214-290-3	dodecyltrimethylammonium bromide	<1,6	Acute Tox. 4, H302 Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335 Aquatic Acute 1, H400 Aquatic Chronic 1, H410	

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

Supply fresh air, consult doctor in case of breathing problems develop.

If on skin

Remove residues with water.

If in eyes

Rinse an open eye with plenty of water for about 15 minutes.

If swallowed

Induce vomiting. 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**

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

None.

5.3. Advice for firefighters

No special advice.

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.

6.2. Environmental precautions

Prevent contamination of the soil and entering surface or ground water.

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6.3. Methods and material for containment and cleaning up

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

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. Observe the principles of work in laboratory. 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.

Storage temperature min 2 °C, max 30 °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 no substances for which occupational exposure limits are set. The mixture contains 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. Sufficient ventilation.

Eye/face protection

Safety goggles are recommended.

Skin protection

Hand protection: Protective gloves resistant to the product. Contaminated skin should be washed thoroughly.

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**

Physical state	liquid
Colour	colourless
Odour	odorless
Melting point/freezing point	0 °C
Boiling point or initial boiling point and boiling range	100 °C
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	6 (undiluted)
Kinematic viscosity	data not available
Solubility in water	miscible
Partition coefficient n-octanol/water (log value)	data not available
Vapour pressure	data not available
Density and/or relative density	
Density	1.01 g/cm ³ at 20 °C
Relative vapour density	data not available
Particle characteristics	data not available

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9.2. Other information

not available

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

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

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

10.5. Incompatible materials

Protect against strong acids, bases and oxidizing agents.

10.6. Hazardous decomposition products

No decomposition products known.

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

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.

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**

Harmful to aquatic life with long lasting effects. Data for the components of the mixture are not available.

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.

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

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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**

H302	Harmful if swallowed.
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.

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

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
EINECS	European Inventory of Existing Commercial Chemical Substances
EmS	Emergency plan
EU	European Union
EuPCS	European Product Categorisation System
IATA	International Air Transport Association

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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
log Kow	Octanol-water partition coefficient
OEL	Occupational Exposure Limits
PBT	Persistent, Bioaccumulative and Toxic
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)
Eye Irrit.	Eye irritation
Skin Irrit.	Skin irritation
STOT SE	Specific target organ toxicity - single exposure

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.

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.