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

1.1. Product identifier — ELite H580 Lyse 1

Substance / mixture	mixture
Number	HEM00020
UFI	H5DF-W31H-1N47-RYV7

Other mixture names

ELite H580 Lyse1
Lyse1-H580

1.2. Relevant identified uses of the substance or mixture and uses advised against

Mixture's intended use

ELite H580 Lyse 1 is used to dissolve red blood cells for counting hemoglobin and white blood cells on hematology analysers ELite 580.

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 number	CZ26918846
Phone	+420 517 077 111
Email	msds@erba.com
Web address	www.erba.com

Competent person responsible for the safety data sheet

Name	Erba Lachema s.r.o.
Email	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.

Eye Irrit. 2, H319
Aquatic Chronic 2, H411

Most serious adverse effects on human health and the environment

Causes serious eye irritation. Toxic to aquatic life with long lasting effects.

2.2. Label elements

Hazard pictogram



Signal word

Warning

Hazard statements

H319	Causes serious eye irritation.
H411	Toxic to aquatic life with long lasting effects.

Precautionary statements

P273	Avoid release to the environment.
P280	Wear eye protection.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

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. Does not contain any PMT or vPvM components.

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: 1119-94-4 EC: 214-290-3	dodecyltrimethylammonium bromide	3.5	Acute Tox. 4, H302 Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335 Aquatic Acute 1, H400 Aquatic Chronic 1, H410	
Index: 607-001-00-0 CAS: 64-18-6 EC: 200-579-1	formic acid	<1.3	Flam. Liq. 3, H226 Met. Corr. 1, H290 Acute Tox. 4, H302 Skin Corr. 1A, H314 Eye Dam. 1, H318 Acute Tox. 3, H331 Specific concentration limit: Skin Irrit. 2, H315: 2 % ≤ C < 10 % Eye Irrit. 2, H319: 2 % ≤ C < 10 % Skin Corr. 1A, H314: C ≥ 90 % Skin Corr. 1B, H314: 10 % ≤ C < 90 % Flam. Liq. 3, H226: C > 85 % ATE Inhalation (vapor) = 7,4 mg/l ATE Oral = 500 mg/kg bw Eye Dam. 1, H318: C ≥ 10 %	1, 2
Index: 603-117-00-0 CAS: 67-63-0 EC: 200-661-7	propan-2-ol	<0.8	Flam. Liq. 2, H225 Eye Irrit. 2, H319 STOT SE 3, H336	2
Index: 607-705-00-8 CAS: 65-85-0 EC: 200-618-2	benzoic acid	0.3	Skin Irrit. 2, H315 Eye Dam. 1, H318 STOT RE 1, H372 (lungs) (inhalation)	

Notes

1 *Note B: Some substances (acids, bases, etc.) are placed on the market in aqueous solutions at various concentrations and, therefore, these solutions require different classification and labelling since the hazards vary at different concentrations. In Part 3 entries with Note B have a general designation of the following type: 'nitric acid … %'. In this case the supplier must state the percentage concentration of the solution on the label. Unless otherwise stated, it is assumed that the percentage concentration is calculated on a weight/weight basis.*

2 *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. 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.

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

Inhalation of hazardous degradation (pyrolysis) products may cause serious health damage.

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 contact with the substance. Wear personal protection equipment. Do not breathe vapour/aerosol. Observe the principles of work safety in chemical laboratories.

6.2. Environmental precautions

Do not allow to enter drains. Prevent contamination of the soil and entering surface or ground water.

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

Avoid release to the environment. Follow the principles of work in the laboratory. Follow normal work procedures for handling chemicals and mixtures. Do not eat, do not drink, do not smoke. Use personal protective equipment see Section 8.

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

The specific requirements or rules relating to the substance/mixture

The product is stable for 2 years while maintaining a storage temperature of 2-30 ° C. Dispose of the opened container after 60 days.

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 473/2025 Coll.**

Substance name (component)	Type	Value
formic acid (CAS: 64−18−6)	PEL	9 mg/m³
	PEL	4,7 ppm
	NPK-P	18 mg/m³
	NPK-P	9,4 ppm
propan−2−ol (CAS: 67−63−0)	PEL	500 mg/m³
	PEL	200 ppm
	NPK-P	1000 mg/m³
	NPK-P	400 ppm

Notes

Irritating to mucous membranes (eyes, respiratory system) and skin.

European Union **Commission Directive 2006/15/EC**

Substance name (component)	Type	Value
formic acid (CAS: 64−18−6)	OEL 8 hours	9 mg/m³
	OEL 8 hours	5 ppm

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.

Skin protection

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

Respiratory protection

Under good ventilation/ exhaustion at the workplace, the use of these products should not require respiratory protection.

Thermal hazard

Not available.

Environmental exposure controls

Observe usual measures for protection of the environment, see Section 6.2. Collect spillage.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	liquid
Colour	colourless
Odour	data not available
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	2.3 (undiluted at 25 °C)
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	
Density	data not available
Relative density	data not available
Relative vapour density	data not available
Particle characteristics	data not available
Form	transparent

9.2. Other information

Evaporation rate	data not available
Oxidising properties	not available
Explosive properties	data not available
Vapour density	data 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 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

Hazardous substances in concentrations exceeding exposure limits may cause acute inhalation poisoning, depending on the concentration and duration of exposure. 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. Data for the components of the mixture are not available.

ELite H580 Lyse 1						
Route of exposure	Parameter	Value	Exposure time	Species	Sex	Value determination
Oral	ATE	11236 mg/kg				Calculation of value
Inhalation (vapor)	ATE	643.5 mg/l				Calculation of value

formic acid						
Route of exposure	Parameter	Value	Exposure time	Species	Sex	Value determination
Inhalation (vapor)	ATE	7.4 mg/l				
Oral	ATE	500 mg/kg bw				

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

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

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.

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

Endocrine disrupting properties

Based on the available data, the criteria for classification of the mixture are not met. Does not contain any components that may cause endocrine disruption for humans.

Other information

not available

SECTION 12: Ecological information

12.1. Toxicity

Toxic 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

Based on the available data, the criteria for classification of the mixture are not met. Does not contain any PMT or vPvM components.

12.5. Results of PBT and vPvB assessment

Based on the available data, the criteria for classification of the mixture are not met. Does not contain any PBT or vPvB components. 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

Based on the available data, the criteria for classification of the mixture are not met. Does not contain any components that may cause endocrine disruption in the environment.

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. 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. 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

UN 3082

14.2. UN proper shipping name

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (dodecyltrimethylammonium bromide)

14.3. Transport hazard class(es)

9 Miscellaneous dangerous substances and articles

14.4. Packing group

III

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

Additional information

Hazard identification No.	**90**
UN number	**3082**
Classification code	M6
Safety signs	9+hazardous for the environment



Tunnel restriction code	(-)

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

H225	Highly flammable liquid and vapour.
H226	Flammable liquid and vapour.
H290	May be corrosive to metals.
H302	Harmful if swallowed.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H331	Toxic if inhaled.
H335	May cause respiratory irritation.
H336	May cause drowsiness or dizziness.
H372	Causes damage to the lungs through prolonged or repeated exposure if inhaled.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
H411	Toxic to aquatic life with long lasting effects.

Guidelines for safe handling used in the safety data sheet

P273	Avoid release to the environment.
P280	Wear eye protection.

P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

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	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)
ATE	Acute toxicity estimate
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
EmS	Emergency Response Procedures for Ships Carrying Dangerous Goods
EU	European Union
EuPCS	European Product Categorisation System
Eye Dam.	Serious eye damage
Eye Irrit.	Eye irritation
Flam. Liq.	Flammable liquid
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
log Kow	Octanol-water partition coefficient
Met. Corr.	Corrosive to metals
NPK	Maximum admissible concentration
OEL	Occupational Exposure Limits
PBT	Persistent, bioaccumulative and toxic
PEL	Permissible Exposure Limit
PMT	Persistent, mobile and toxic
ppm	Parts per million
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RID	Regulation concerning the International Carriage of Dangerous Goods by Rail
Skin Corr.	Skin corrosion
Skin Irrit.	Skin irritation
STOT RE	Specific target organ toxicity - repeated exposure
STOT SE	Specific target organ toxicity - single exposure
UN number	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
vPvM	Very persistent and very mobile

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

For in vitro diagnostic use only.

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 7.0 replaces the SDS version from Tuesday, 7 January 2025. Changes were made in sections 2, 13, 15 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.