

LEUCODIF_R1

Creation date	16th January 2015		
Revision date	07th September 2023	Version	3.0

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

Substance / mixture	LEUCODIF_R1
Number	mixture
UFI	BLT00083
Other mixture names	9VK8-UJVT-8E76-6GPS
	LEUCODIF 200; LEUCODIF

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

Reagent 1 is a part of kit Leucodif for fast staining of blood smears.

Main intended use

PC-MED-OTH Other medical devices

Secondary uses

PC-TEC-19 Reagents and laboratory chemicals

The use descriptors

PC 21 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.

Flam. Liq. 2, H225
Acute Tox. 3, H301+H311+H331
STOT SE 1, H370

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

Most serious adverse physico-chemical effects

Highly flammable liquid and vapour.

Most serious adverse effects on human health and the environment

Causes damage to organs. Toxic if swallowed, in contact with skin or if inhaled.

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2.2. Label elements**Hazard pictogram****Signal word**

Danger

Hazardous substances

methanol

Hazard statements

H225	Highly flammable liquid and vapour.
H370	Causes damage to organs.
H301+H311+H331	Toxic if swallowed, in contact with skin or if inhaled.

Precautionary statements

P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P233	Keep container tightly closed.
P260	Do not breathe vapours.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P301+P310	IF SWALLOWED: Immediately call a POISON CENTER or doctor.
P308+P311	IF exposed or concerned: Call a POISON CENTER or doctor.

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: 603-001-00-X CAS: 67-56-1 EC: 200-659-6	methanol	<100	Flam. Liq. 2, H225 Acute Tox. 3, H301+H311+H331 STOT SE 1 (**), H370 Specific concentration limit: STOT SE 1, H370: C ≥ 10 % STOT SE 2, H371: 3 % ≤ C < 10 %	1, 2, 3

Notes

** another exposure route cannot be ruled out

1 A substance for which exposure limits are set.

2 Substance for which biological limit values exist.

3 The use of the substance is restricted by Annex XVII of REACH Regulation

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. If unconscious, put the person in the stabilized (recovery) position on his side with his head slightly bent backwards and make sure that airways are free; never induce vomiting. If the person vomits by himself, make sure that the vomit is not inhaled. In life threatening conditions first of all provide resuscitation of the affected person and ensure medical assistance. Respiratory arrest - provide artificial respiration immediately. Cardiac arrest - provide indirect cardiac massage immediately.

If inhaled

Take care of your own safety, do not let the affected person walk! Terminate the exposure immediately; move the affected person to fresh air. Beware of the contaminated clothes. Depending on the situation, call the medical rescue service and ensure medical treatment considering the frequent need of further observation for at least 24 hours. If breathing stops, start artificial respiration immediately.

If on skin

Remove contaminated clothes. Take off any rings, watches, bracelets before or during washing if worn in the contaminated areas of the skin. Depending on the situation, call the medical rescue service and always ensure medical treatment. Rinse contaminated areas with a flow of water, lukewarm at best, for 10-30 minutes; do not use any brush, soap or neutralizers. Rinse skin with water/shower.

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. No neutralization should be performed in any case! Rinsing should be continued for 10-30 minutes from the inner to the outer eye corner to make sure that the other eye is not involved. Depending on the situation, call medical rescue service or ensure medical treatment as promptly as possible. Everyone must be referred for treatment even if affected only a little.

If swallowed

Vomiting should be induced in the person only if conscious, within 1 hour from ingestion. If in doubt whether vomiting should be induced, contact the Toxicological Information Centre and give information about the substances or composition of the product as provided on the original packaging or in the safety data sheet of the product. AFTER INGESTION OF TOXIC OR HIGHLY TOXIC SUBSTANCES, GIVE 10-20 CRUSHED ACTIVATED CHARCOAL TABLETS MIXED IN WATER WITHIN 5 MINUTES - regardless of whether vomiting has been induced. Give the affected person ethanol to drink (1 glass of 40% alcoholic drink). Seek medical attention immediately, mention methanol ingestion. Repeat ethanol drinking and maintain 1‰ alcohol.

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

Irritant effect, cough, headache.

If on skin

Skin drying.

If in eyes

May cause severe irritation.

If swallowed

Drowsiness, dizziness, narcosis, nausea, vomiting, blindness, visual impairment, coma. The fatal dose for humans is 30 ml, a dose of 7-15 ml can cause blindness.

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

In the event of fire, carbon monoxide, carbon dioxide and other toxic gases may arise. Inhalation of hazardous degradation (pyrolysis) products may cause serious health damage. Flammable liquid. Vapors are highly flammable and when mixed with air form a toxic and explosive mixture heavier than air. Igniting this mixture causes the fire to spread over great distances.

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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. Closed containers with the product near the fire should be cooled with water. 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**

Provide sufficient ventilation. Highly flammable liquid and vapour. Remove all ignition sources. Use personal protective equipment for work. Follow the instructions in the Sections 7 and 8. Do not inhale vapours. Prevent contact with skin and eyes.

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

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 formation of gases and vapours in flammable or explosive concentrations and concentrations exceeding the occupational exposure limits. The product should be used only in the areas where it is not in contact with open fire and other ignition sources. Use non-sparking tools. Use of antistatic clothes and footwear is recommended. Do not inhale aerosols. Prevent contact with skin and eyes. No smoking. Use only non-sparking tools. Do not eat, drink or smoke when using this product. Wash hands and exposed parts of the body thoroughly after handling. Use only outdoors or in a well-ventilated area. Use personal protective equipment as per Section 8. Observe valid legal regulations on safety and health protection. Ground and bond container and receiving equipment. Use explosion-proof electrical/ventilating/lighting equipment. Take precautionary measures against static discharge.

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. Do not expose to sunlight. Store locked up. Keep container tightly closed. Keep away from sources of heating, ignition and direct sunlight.

Storage class

6,1C - Combustible toxic substances or substances with chronic effect

Storage temperature

min 2 °C, max 25 °C

The specific requirements or rules relating to the substance/mixture

Solvent vapours are heavier than air and accumulate especially near the floor where they may form an explosive mixture with the air.

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
methanol (CAS: 67-56-1)	PEL	250 mg/m ³	0,751	skin penetration is significantly involved during exposure

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Czech Republic

Government Regulation 195/2021 Coll.

Substance name (component)	Type	Value	Conversion for ppm	Note
methanol (CAS: 67-56-1)	NPK-P	1000 mg/m ³	0,751	skin penetration is significantly involved during exposure

European Union

Commission Directive 2006/15/EC

Substance name (component)	Type	Value	Note
methanol (CAS: 67-56-1)	OEL 8 hours	260 mg/m ³	Skin
	OEL 8 hours	200 ppm	

Biological limit values

Czech Republic

Decree No. 107/2017 Coll.

Name	Parameter	Value	Tested material	Time of sampling
methanol (CAS: 67-56-1)	methanol	15 mg/l	Urine	End of shift
		0,47 mmol/l		

8.2. Exposure controls

Follow the usual measures intended for health protection at work and especially for good ventilation. This can be achieved only by local suction or efficient general ventilation. 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 or face shield (based on the nature of the work performed).

Skin protection

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

Respiratory protection

Respirator. Mask with a filter against organic vapours in a poorly ventilated environment. Use insulating breathing apparatus when the exposition limits of the substances are exceeded or at the place with insufficient ventilation. 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	green
Odour	containing alcohol
Melting point/freezing point	-98 °C
Boiling point or initial boiling point and boiling range	65 °C
Flammability	Highly flammable liquid and vapor.
Lower and upper explosion limit	
bottom	5.5 %
upper	44 %
Flash point	11 °C
Auto-ignition temperature	455 °C
Decomposition temperature	data not available

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pH	data not available
Kinematic viscosity	data not available
Viscosity	0.579 mPa,s
Solubility in water	data not available
Partition coefficient n-octanol/water (log value)	low Pow:-0.77
Vapour pressure	128 hPa at 20 °C
Density and/or relative density	
Density	0.791 g/cm ³
Relative vapour density	data not available
Particle characteristics	data not available

9.2. Other information

Vapour density	1.11
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SECTION 10: Stability and reactivity**10.1. Reactivity**

The mixture is highly flammable.

10.2. Chemical stability

The product is stable under normal conditions.

10.3. Possibility of hazardous reactions

Explosive reaction with strong oxidizing reagents.

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 inorganic alkalines, alkaline metals, barium hydroxide, bromoform, strong reducing or 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

Causes damage to organs. Toxic if swallowed, in contact with skin or if inhaled.

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Route of exposure	Parameter	Value	Exposure time	Species	Sex	Value determination
Oral	ATE	100 mg/kg				Calculation of value
Dermal	ATE	300 mg/kg				Calculation of value
Inhalation (vapor)	ATE	3 mg/l				Calculation of value

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.

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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

Causes damage to organs.

Toxicity for specific target organ - repeated exposure

Based on available data the classification criteria are not met.

Aspiration hazard

Based on available data the classification criteria 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**

not available

12.2. Persistence and degradability

Easily biodegradable (exposure time 5 days - 72%)

12.3. Bioaccumulative potential

Bioaccumulation is not expected (log Pow <1)

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. 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 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 1230

14.2. UN proper shipping name

METHANOL

14.3. Transport hazard class(es)

3 Flammable liquids

14.4. Packing group

II - substances presenting medium danger

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.

336

UN number

1230

Classification code

FT1

Safety signs

3+6.1

**Air transport - ICAO/IATA**

Packaging instructions passenger

352

Cargo packaging instructions

364

Marine transport - IMDG

EmS (emergency plan)

F-E, S-D

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).

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Restrictions pursuant to Annex XVII of Regulation (EC) No. 1907/2006 (REACH), as amended

methanol

Restriction	Conditions of restriction
69	Shall not be placed on the market to the general public after 9 May 2019 in windscreen washing or defrosting fluids, in a concentration equal to or greater than 0,6 % by weight.

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.
H370 Causes damage to organs.
H371 May cause damage to organs.
H301+H311+H331 Toxic if swallowed, in contact with skin or if inhaled.

Guidelines for safe handling used in the safety data sheet

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P233 Keep container tightly closed.
P260 Do not breathe vapours.
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P301+P310 IF SWALLOWED: Immediately call a POISON CENTER or doctor.
P308+P311 IF exposed or concerned: Call a POISON CENTER or doctor.

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
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
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

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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
Flam. Liq.	Flammable liquid
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

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 3.0 replaces the SDS version from 02 September 2022. Changes were made in sections 2, 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.