

Safety Data Sheet

according to the European Parliament and Council Regulation (EC) No. 1907/2006 (REACH), Article 31, Annex II

Date of issue: 24.03.2014 Date of review: 22.09.2014 Page 1 of 10 pages Version: 1

Name of the mixture: **LEUCODIF 200**

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

1.1 Product identifier

LEUCODIF 200	
Catalog Number	BLT00083
Reagent 1	1 × 200 ml
Reagent 2	1 × 200 ml
Reagent 3	1 × 200 ml
Reagent 4	1 × 2 g (5 tablets)

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

Set for fast staining of blood smears. The mixture is intended for professional use.

1.3 Details of the supplier of the safety data sheet

Name of manufacturer: Erba Lachema s.r.o.
Place of business: Karasek 2219/1d, 621 00 Brno, CZ
ID no.: 26918846
Phone: +420 517 077 111
Fax: +420 517 077 077
E-mail: msds@erbalachema.com

1.4 Emergency telephone number

Erba Lachema s.r.o.

Phone: +420 517 077 556 (service only during business hours)

Toxicological Information Centre (TIS), Na Bojisti 1, 128 01 Prague, CZ

Phone: +420 224 919 293 or +420 224 915 402 (service available 24 hours a day)

SECTION 2: Hazards identification

The kit **LEUCODIF 200** is classified as dangerous according to EU Directives 1999/45/EC as amended.

2.1 Classification of the substance or mixture

Reagent 1

The mixture of reagent 1 is classified as toxic and highly flammable.

R11 Highly flammable

R23/24/25 Toxic by inhalation, in contact with skin and if swallowed.

R39/23/24/25 Toxic: danger of very serious irreversible effects through inhalation, in contact with skin and if swallowed.

Reagent 2

The mixture of reagent 2 is not classified as dangerous according to EU Directives 1999/45/EC as amended

Reagent 3

The mixture of reagent 3 is not classified as dangerous according to EU Directives 1999/45/EC as amended

Safety Data Sheet

according to the European Parliament and Council Regulation (EC) No. 1907/2006 (REACH), Article 31, Annex II

Date of issue: 24.03.2014	Date of review: 22.09.2014	Page 2 of 10 pages	Version: 1
---------------------------	----------------------------	--------------------	------------

Name of the mixture: **LEUCODIF 200**

Reagent 4

The mixture of reagent 1 is classified as irritant.

R36/37/38 Irritating to eyes, respiratory system and skin.

2.2 Label elements

Labelling according to EU Directive 1999/45/EC

Reagent 1



Toxic



Highly flammable

Risk phrases (R):

R11	Highly flammable
R23/24/25	Toxic by inhalation, in contact with skin and if swallowed.
R39/23/24/25	Toxic: danger of very serious irreversible effects through inhalation, in contact with skin and if swallowed.

Safety phrases (S):

S7	Keep container tightly closed.
S16	Keep away from sources of ignition – No smoking.
S36/37	Wear suitable protective clothing and gloves.
S45	In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

Reagent 4



Irritant

Risk phrases (R):

R36/37/38 Irritating to eyes, respiratory system and skin.

Safety phrases (S):

S26	In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S36	Wear suitable protective clothing.

2.3 Other hazards

None

Safety Data Sheet

according to the European Parliament and Council Regulation (EC) No. 1907/2006 (REACH), Article 31, Annex II

Date of issue: 24.03.2014	Date of review: 22.09.2014	Page 3 of 10 pages	Version: 1
---------------------------	----------------------------	--------------------	------------

Name of the mixture: **LEUCODIF 200**

SECTION 3: Composition/information on ingredients

3.2 Mixtures

The reagent 1 contains the following hazardous substances:

Substance name	Content (% of weight)	CAS number EC number Index number	Classification according to (EC) No. 67/548 EEC
			Classification according to (EC) No. 1272/2008
Methanol*	100	67-56-1 200-659-6 603-001-00-X	F; R11 T; R23/24/25-39/23/24/25
			Flam. Liq. 2, H225 Acute Tox. 3, H301 Acute Tox. 3, H311 Acute Tox. 3, H331 STOT SE 1, H370

The reagent 4 contains the following hazardous substances:

Substance name	Content (% of weight)	CAS number EC number Index number	Classification according to (EC) No. 67/548 EEC
			Classification according to (EC) No. 1272/2008
Sodium phosphate dibasic dihydrate	67	10028-24-7 231-448-7 -	Xi; R36/37/38
			-

*)Substance with exposure limits (exposure limits are listed in Chapter 8.1)

For a full text of R-phrases, S-phrases, H-phrases and P-phrases see Section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

When working with the mixture, take care of personal hygiene and prevent contamination of work clothing and skin. If you have any doubts or when symptoms persist, seek medical attention.

Exposure by inhalation

Discontinue the exposure, remove casualty to fresh air, keep at rest and seek medical advice.

Exposure by contact with skin

Take off all contaminated clothing. After contact with skin, wash immediately with soap and water.

Exposure by contact with eyes

Rinse an open eye (hold eyelids with fingers) with plenty of water for about 15 minutes, transfer casualty to a specialist.

Exposure by ingestion

Rinse mouth with water, drink 1/2 l of lukewarm water, seek medical attention immediately, do not induce vomiting.

4.2 Most important symptoms and effects, both acute and delayed

None

4.3 Indication of any immediate medical attention and special treatment needed

No data available

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media

Safety Data Sheet

according to the European Parliament and Council Regulation (EC) No. 1907/2006 (REACH), Article 31, Annex II

Date of issue: 24.03.2014

Date of review: 22.09.2014

Page 4 of 10 pages

Version: 1

Name of the mixture: **LEUCODIF 200**

Water spray, foam, dry powder, carbon dioxide

Unsuitable extinguishing media

Direct stream of water.

5.2 Special hazards arising from the substance or mixture

Flammable substance. During thermal decomposition toxic products are generated. Direct stream of water can cause the burning liquid to spill. Vapors may extend to a considerable distance to source of ignition and flame may burst backward. Fumes in combination with air can form an explosive mixture. Heat can cause an explosion of package.

5.3 Advice for firefighters

Self-contained breathing apparatus, chemical-protective clothing.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

6.1.1 For ordinary workers, except emergency staff

Use personal protective equipment, see section 8. Observe the principles of work safety in chemical laboratories. Do not eat, drink or smoke.

6.1.2 For the staff of emergency responders

Isolate and mark the spill site, order all the people out of the place, who do not participate in the rescue work. Remove all possible sources of ignition, turn off vehicle engines, no smoking and open flames, use non-sparking tools and lamps. Use all recommended personal protective equipment during rescue work.

6.2 Environmental precautions

Reagent 1: Avoid contamination of surface water, groundwater and soil. Do not discharge into the drains, danger of explosion.

6.3 Methods and material for containment and cleaning up

Absorb spilled agent with a suitable inert material (sand, earth, vapex) and store contaminated material in containers for collection of hazardous waste. For waste disposal see section 13.

Sweep solid reagent and store in containers for collection of hazardous waste. For waste disposal see section 13.

6.4 Reference to other sections

See section 7, 8 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Ensure sufficient ventilation of the space, use personal protective equipment, no smoking and open flames, avoid release to the environment.

7.2 Conditions for safe storage, including any incompatibilities

Store in dry and covered stores at a temperature between +2 °C and +25 °C.

7.3 Specific end use(s)

The kit is designed for *in vitro* diagnostic devices.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Exposure limit values of the mixture components according to Government Decree No. 361/2007 Coll.

Safety Data Sheet

according to the European Parliament and Council Regulation (EC) No. 1907/2006 (REACH), Article 31, Annex II

Date of issue: 24.03.2014	Date of review: 22.09.2014	Page 5 of 10 pages	Version: 1
---------------------------	----------------------------	--------------------	------------

Name of the mixture: **LEUCODIF 200**

CAS	Substance name	PEL	NPK-P	Note	Conversion factor for ppm
		mg/m ³	mg/m ³		
67-56-1	Methanol	250	1000	D	0.754

*PEL - Permissible exposure limits; NPK-P - the maximum permissible concentration; D - a significant penetration of the substance through the skin or a strong irritating effect on the skin during exposure; S - the substance has a sensitizing effect; P - serious late effects of the substance cannot be excluded; * - the physico-chemical properties (e.g. explosiveness) are taken into account for NPK-P.*

Exposure limit values in the workplace according to Directive No. 2006/15/EC

CAS	Substance name	Limit values				Note
		8 hrs		Short period		
		mg/m ³	ppm	mg/m ³	ppm	
67-56-1	Methanol	260	200	-	-	Skin

Limit values for indicators of biological exposure tests in urine for the product according to Decree No. 432/2003 Coll.

Substance name	Indicator	Limit values	Sampling time
Methanol	Methanol	15 mg/l 0.47 mmol/l	End of shift

8.2 Exposure controls

Appropriate engineering controls

None

Personal protective equipment

- a) Respiratory protection: Not required with adequate ventilation
- b) Hand protection: Protective gloves - resistant to caustic substances
- c) Eye protection: Safety goggles
- d) Skin protection: Protective clothing

Environmental exposure controls

To eliminate the emergency conditions, have pre-prepared a decontamination mixture and appropriate collection vessels for reaction residues. Dispose of reaction residues and decontaminated mixtures as hazardous waste water in accordance with relevant legal regulations.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Reagent 1

Appearance.....	pale green liquid
Odour.....	no data available
Odour Threshold	no data available
pH (at 20 °C)	no data available
Melting point/freezing point.....	no data available
Initial boiling point and boiling range (°C)...	64.6
Flash point (°C)	11
Evaporation rate	no data available
Flammability (solid, gas).....	no data available
Upper/lower flammability or explosive limits	no data available
Vapour pressure (hPa).....	128
Vapour density	no data available
Relative density (kg·m ⁻³)	0.79
Water solubility	no data available

Safety Data Sheet

according to the European Parliament and Council Regulation (EC) No. 1907/2006 (REACH), Article 31, Annex II

Date of issue: 24.03.2014	Date of review: 22.09.2014	Page 6 of 10 pages	Version: 1
---------------------------	----------------------------	--------------------	------------

Name of the mixture: **LEUCODIF 200**

Partition coefficient: n-octanol/water..... no data available
 Autoignition temperature (°C) no data available
 Decomposition temperature (°C) no data available
 Viscosity..... no data available
 Explosive properties..... no data available
 Oxidizing properties..... no data available

Reagent 2

Appearance..... red liquid
 Odour..... no data available
 Odour Threshold no data available
 pH (at 20 °C) no data available
 Melting point/freezing point..... no data available
 Initial boiling point and boiling range (°C)... no data available
 Flash point (°C) no data available
 Evaporation rate no data available
 Flammability (solid, gas)..... no data available
 Upper/lower flammability or explosive limits no data available
 Vapour pressure (hPa)..... no data available
 Vapour density no data available
 Relative density (kg·m⁻³) no data available
 Water solubility no data available
 Partition coefficient: n-octanol/water..... no data available
 Autoignition temperature (°C) no data available
 Decomposition temperature (°C) no data available
 Viscosity..... no data available
 Explosive properties..... no data available
 Oxidizing properties..... no data available

Reagent 3

Appearance..... dark blue liquid
 Odour..... no data available
 Odour Threshold no data available
 pH (at 20 °C) no data available
 Melting point/freezing point..... no data available
 Initial boiling point and boiling range (°C)... no data available
 Flash point (°C) no data available
 Evaporation rate no data available
 Flammability (solid, gas)..... no data available
 Upper/lower flammability or explosive limits no data available
 Vapour pressure (hPa)..... no data available
 Vapour density no data available
 Relative density (kg·m⁻³) no data available
 Water solubility no data available
 Partition coefficient: n-octanol/water..... no data available
 Autoignition temperature (°C) no data available
 Decomposition temperature (°C) no data available
 Viscosity..... no data available

Safety Data Sheet

according to the European Parliament and Council Regulation (EC) No. 1907/2006 (REACH), Article 31, Annex II

Date of issue: 24.03.2014

Date of review: 22.09.2014

Page 7 of 10 pages

Version: 1

Name of the mixture: **LEUCODIF 200**

Explosive properties..... no data available

Oxidizing properties..... no data available

Reagent 4

Appearance..... white solid

Odour..... no data available

Odour Threshold no data available

pH (at 20 °C)..... 8

Melting point/freezing point..... no data available

Initial boiling point and boiling range (°C)..... no data available

Flash point (°C)..... no data available

Evaporation rate no data available

Flammability (solid, gas)..... no data available

Upper/lower flammability or explosive limits no data available

Vapour pressure (hPa)..... no data available

Vapour density no data available

Relative density (kg·m⁻³) no data available

Water solubility..... no data available

Partition coefficient: n-octanol/water..... no data available

Autoignition temperature (°C) no data available

Decomposition temperature (°C) no data available

Viscosity..... no data available

Explosive properties..... no data available

Oxidizing properties..... no data available

9.2 Other information

None

SECTION 10: Stability and reactivity

Under normal conditions of use and storage the mixture is stable.

10.1 Reactivity

No data available

10.2 Chemical stability

No data available

10.3 Possibility of hazardous reactions

No data available

10.4 Conditions to avoid

Reagent 1: Do not store near heat sources, sources of sparking and open flame.

10.5 Incompatible material

Reagent 1: Inorganic bases, strong oxidizing agents, strong reducing agents, alkali metal, barium hydroxide, bromine, bromoform, boron trifluoride.

10.6 Hazardous decomposition products

In case of fire carbon oxides are generated.

Safety Data Sheet

according to the European Parliament and Council Regulation (EC) No. 1907/2006 (REACH), Article 31, Annex II

Date of issue: 24.03.2014

Date of review: 22.09.2014

Page 8 of 10 pages

Version: 1

Name of the mixture: **LEUCODIF 200**

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Reagent 1: Toxic: danger of very serious irreversible effects through inhalation, in contact with skin and if swallowed. Toxic by inhalation, in contact with skin and if swallowed.

Rat oral LD ₅₀ (mg·kg ⁻¹).....	5 628
Rabbit dermal LD ₅₀ (mg·kg ⁻¹).....	15 800
Rat inhalation LD ₅₀ (mg·6 ⁻¹).....	64 000/4hrs
Rat inhalation TLS (g·kg ⁻¹)	not applicable

SECTION 12: Ecological information

12.1 Toxicity

Reagent 1: Acute toxicity

LC ₅₀ 96 hrs, fish (mg·l ⁻¹)	15 400
EC ₅₀ 48 hrs, daphnia (mg·l ⁻¹).....	>10 000
IC ₅₀ 72 hrs algae (mg·l ⁻¹)	8 000
CHSK	not applicable
BSK ₅	not applicable

12.2 Persistence and degradability

Not applicable.

12.3 Bioaccumulative potential

Not applicable.

12.4 Mobility in soil

Not applicable.

12.5 Results of PBT and vPvB assessment

The mixture does not have properties of PBT and vPvB. This statement was considered from substances that do not have properties of PBT and vPvB.

12.6 Other adverse effects

No data available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Dispose of in compliance with applicable regulations for hazardous waste management. Incinerate residues of the mixture in a hazardous waste incinerator.

Contaminated packaging must be treated as hazardous waste. Dispose of by incinerating in a hazardous waste incinerator.

SECTION 14: Transport information

Not governed by regulations for transport of dangerous goods (ADR).

14.1 UN number

ADR/RID: -

IMDG: -

ICAO/IATA: -

14.2 UN proper shipping name

ADR/RID: -

Safety Data Sheet

according to the European Parliament and Council Regulation (EC) No. 1907/2006 (REACH), Article 31, Annex II

Date of issue: 24.03.2014

Date of review: 22.09.2014

Page 9 of 10 pages

Version: 1

Name of the mixture: **LEUCODIF 200**

IMDG: -

ICAO/IATA: -

14.3 Transport hazard class(es)

ADR/RID: -

IMDG: -

ICAO/IATA: -

14.4 Packaging group

ADR/RID: -

IMDG: -

ICAO/IATA: -

14.5 Environmental hazards

ADR/RID: no

IMDG: no

ICAO/IATA: no

14.6 Special precautions for user

No data available.

14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Not transported.

SECTION 15: Regulatory information

This safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006.

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

Regulation (EC) No. 1907/2006 (REACH)

Regulation (EC) No. 1272/2008 (CLP)

EU Directive 1999/45/EC

EU Directive 67/548/EEC

15.2 Chemical safety assessment

No data available.

SECTION 16: Other information

List of R-phrases

R11 Highly flammable

R23/24/25 Toxic by inhalation, in contact with skin and if swallowed.

R39/23/24/25 Toxic: danger of very serious irreversible effects through inhalation, in contact with skin and if swallowed.

List of H-phrases:

H225 Highly flammable liquid and vapour.

H301 Toxic if swallowed.

H311 Toxic in contact with skin.

H331 Toxic if inhaled.

H370 Causes damage to organs.

Safety Data Sheet

according to the European Parliament and Council Regulation (EC) No. 1907/2006 (REACH), Article 31, Annex II

Date of issue: 24.03.2014	Date of review: 22.09.2014	Page 10 of 10 pages	Version: 1
---------------------------	----------------------------	---------------------	------------

Name of the mixture: **LEUCODIF 200**

List of S-phrases:

- | | |
|--------|---|
| S7 | Keep container tightly closed. |
| S16 | Keep away from sources of ignition – No smoking. |
| S26 | In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. |
| S36 | Wear suitable protective clothing. |
| S36/37 | Wear suitable protective clothing and gloves. |
| S45 | In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). |

List of P-phrases:

- | | |
|-----------|--|
| P280 | Wear protective gloves/protective clothing. |
| P233 | Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. |
| P210 | Keep container tightly closed. |
| P301+P310 | IF SWALLOWED: Immediately call a POISON CENTER/doctor. |
| P307+P311 | IF EXPOSED: Call a POISON CENTER or doctor/physician. |

Training instructions

Workers who come into contact with hazardous materials shall be acquainted by the organization, to a necessary extent, with the effects of these substances, with the methods how to treat them, with protective measures, the principles of first aid, necessary sanitation procedures and procedures for liquidation of failures and accidents. Under Article 35 of the European Parliament and Council Regulation (EC) No. 1907/2006, the employer must enable employees or their representatives access to information from the safety data sheet of the substance or mixture the worker uses or the effects of which can be exposed to during his/her work.

Recommended restrictions on use

The mixture is intended for professional use. It should not be used for purposes other than those listed under 1.2.

Further information

Information given is based on our best knowledge and is intended to describe the product for the purposes of safety of transporting and handling only. It should not be therefore construed as guaranteeing any specific property of the product. It is the responsibility of the user to observe all current regulations and consider recommendations on the use of application of product.

Declaration

The safety data sheet contains basic data corresponding to the present state of our knowledge and experience, in accordance with applicable regulations. The foregoing information was gathered with the utmost care, but that does not mean that it is complete and should be used as the only correct information. Erba Lachema s.r.o. is not responsible for any damages caused by improper use and handling of the mixture.