zone GLUKO

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Revision date		Version	1.0

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

1.1. Product identifier — zone GLUKO

Substance / mixture — mixture

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

Mixture's intended use

Diagnostic strips are intended for semi-quantitative analysis of urine. The GLUKO zone is used in clinical biochemistry for the semi-quantitative determination of glucose in urine. Diagnostic strips are intended for in vitro diagnostic use by an authorized and professionally trained person.

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 then 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

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 not classified as dangerous according to Regulation (EC) No 1272/2008.

2.2. Label elements

none

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

A solid mixture of substances on a carrier. Mixture of substances 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: 6381-92-6 EC: 205-358-3	Disodium EDTA	<0,05	Acute Tox. 4, H332 STOT RE 2, H373	
CAS: 77-86-1 EC: 201-064-4	Tris(hydroxymethyl)aminomethane	<0,03	Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335	

Identification numbers	Substance name	Content in % weight	Classification according to Regulation (EC) No 1272/2008	Note
CAS: 54827-17-7 EC: 259-364-6	3',5,5'-tetramethylbenzidine	<0,02	Acute Tox. 4, H302+H312+H332 Muta. 2, H341 STOT SE 2, H371	
CAS: 1119-94-4 EC: 214-290-3	dodecyltrimethylammonium bromide	<0,01	Acute Tox. 4, H302 Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335 Aquatic Acute 1, H400 Aquatic Chronic 1, H410	
CAS: 122-18-9 EC: 204-526-3	Cetalkonium chloride	0,009	Acute Tox. 4, H302+H312 Skin Corr. 1C, H314 Aquatic Acute 1, H400	
CAS: 126-92-1 EC: 204-812-8	Sodium etasulfate	0,006	Skin Irrit. 2, H315 Eye Irrit. 2, H319	
CAS: 9001-37-0 EC: 232-601-0	β-D-Glucose	0,002	Resp. Sens. 1, H334	
CAS: 9003-99-0 EC: 232-668-6	Peroxidase	0,002	Skin Sens. 1, H317 Resp. Sens. 1, H334	
CAS: 1934-21-0 EC: 217-699-5	Tartrazine	0,002	Skin Sens. 1, H317 Resp. Sens. 1, H334	
CAS: 9029-44-1	Oxidase, ascorbate	0,001	Resp. Sens. 1, H334	
Index: 604-009-00-6 CAS: 87-66-1 EC: 201-762-9	pyrogallol	0,001	Acute Tox. 4, H302, H312, H332 Muta. 2, H341 Aquatic Chronic 3, H412	

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

Unlikely.

If on skin

Normal washing of the skin is considered sufficient; If nevertheless symptoms do occur, contact a physician.

If in eyes

If used correctly according to the instructions, eye contact is unlikely.

If swallowed

Unlikely. If swallowed rinse mouth with plenty of water provided person is conscious. Call a doctor if you feel unwell.

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

Product is non-combustible. Extinguishing materials should therefore be selected according to surroundings.

Unsuitable extinguishing media

No unsuitable extinguishing media are known.

5.2. Special hazards arising from the substance or mixture

Fires in the immediate vicinity may cause the development of dangerous vapours.

5.3. Advice for firefighters

Use breathing apparatus. Wear protective clothing. The mixture is not flammable. The safety measure should be adapted to the flammable substances in the surroundings.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Observe the principles of work safety in chemical laboratories. Follow the instructions in Sections 7 and 8. Do not eat, drink or smoke.

6.2. Environmental precautions

Due to amount of chemical substances in a mixture, an impact on the environment is not expected.

6.3. Methods and material for containment and cleaning up

Store contaminated material in containers for hazardous waste collection.

6.4. Reference to other sections

See the Section 7, 8 and 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Observe the normal operating procedures for handling chemical substances and mixtures. Observe the principles of safety work in chemical laboratories. Do not eat, drink and smoke in work areas. Wash hands after use. Preventive skin protection (barrier creams/ointments) is recommended. Remove contaminated clothing and protective equipment before entering eating areas.

7.2. Conditions for safe storage, including any incompatibilities

Diagnostic strips must be stored in well-closed original packaging in a dry and dark place at (+2 to +30) °C. The strips must be protected from the effect of air humidity, direct sunlight, elevated temperature and chemical vapors in the laboratory. If these storage conditions are observed, the diagnostic strips can be used until the time indicated on the package.

Storage class	13 - Other non-combustible solids
Storage temperature	min 2 °C, max 30 °C

The specific requirements or rules relating to the substance/mixture

This product is for in vitro diagnostic use only and should be used by trained personnel.

7.3. Specific end use(s)

For professional use only.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

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.

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

Physical state	solid
Colour	mixture containing generic product identifier 'colorant'
Odour	odourless without fragrance
Melting point/freezing point	not applicable
Boiling point or initial boiling point and boiling range	not applicable
Flammability	The product is non-flammable.
Lower and upper explosion limit	data not available
Flash point	not applicable
Auto-ignition temperature	data not available
Decomposition temperature	data not available
pH	data not available
Kinematic viscosity	data not available
Solubility in water	data not available
Partition coefficient n-octanol/water (log value)	data not available
Vapour pressure	data not available
Density and/or relative density	data not available
Relative vapour density	data not available
Particle characteristics	data not available

9.2. Other information

not available

SECTION 10: Stability and reactivity

10.1. Reactivity

Under normal conditions of use and storage the mixture is stable. When used in the standard way, there is not any dangerous reaction with other substances.

10.2. Chemical stability

Sensitivity to light. Hygroscopic. The product is stable until the expiration date shown on the box and on the labels when stored in accordance with section 7.2a.

10.3. Possibility of hazardous reactions

No known hazardous reactions.

10.4. Conditions to avoid

The strips must be protected from the effect of air humidity, direct sunlight, elevated temperature and chemical vapors in the laboratory.

10.5. Incompatible materials

Protect against strong acids, bases and oxidizing agents.

10.6. Hazardous decomposition products

Fires in the immediate vicinity may cause the development of dangerous vapours.

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
Based on available data the classification criteria are not met.

Disodium EDTA					
Route of exposure	Parameter	Value	Exposure time	Species	Sex
Oral	LD_{50}	2800 mg/kg		Rat	
Inhalation	LC_{50}	1000-5000 mg/m³	4 hours	Rat	

β-D-Glucose					
Route of exposure	Parameter	Value	Exposure time	Species	Sex
Intraperitoneally	LD_{50}	3 mg/kg		Mouse	

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.

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
The mixture is not classified as toxic to environment.

Acute toxicity

Disodium EDTA				
Parameter	Value	Exposure time	Species	Environment
EC_{50}	140 mg/l	48 hours	Daphnia (Daphnia magna)	
LC_{50}	320 mg/l	96 hours	Fish (Poecilia reticulata)	

Disodium EDTA				
Parameter	Value	Exposure time	Species	Environment
EC_{50}	56 mg/l	8 hours	Bacteria (Pseudomonas putida)	
NOEC	25.7 mg/l	35 days	Fish (Branchydanio rerio)	
NOEC	25 mg/l	21 days	Daphnia (Daphnia magna)	

Tris(hydroxymethyl)aminomethane				
Parameter	Value	Exposure time	Species	Environment
EC_{50}/LC_{50}	980 mg/l	48 hours	Invertebrates	Fresh water
NOEC	520 mg/l	48 hours	Invertebrates	Fresh water
EC_{50}	397 mg/l	72 hours	Algae	Fresh water
EC_{50}	473 mg/l	48 hours	Algae	Fresh water
NOEC	100 mg/l	72 hours	Algae (Selenastrum capricornutum)	Fresh water

12.2. Persistence and degradability

No data 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. 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

18 01 03* wastes whose collection and disposal is subject to special requirements in order to prevent infection

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

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 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.

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.
H312	Harmful in contact with skin.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H332	Harmful if inhaled.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H335	May cause respiratory irritation.
H341	Suspected of causing genetic defects.
H371	May cause damage to organs.
H373	May cause damage to organs through prolonged or repeated exposure.
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.
H302+H312	Harmful if swallowed or in contact with skin.
H302+H312+H332	Harmful if swallowed, in contact with skin or if inhaled.

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
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
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
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
log Kow	Octanol-water partition coefficient
NOEC	No observed effect concentration
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
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)
Muta.	Germ cell mutagenicity
Resp. Sens.	Respiratory sensitization
Skin Corr.	Skin corrosion
Skin Sens.	Skin sensitization
STOT RE	Specific target organ toxicity - repeated exposure
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.