

TOTAL PROTEIN_R1

Creation date	19th September 2016	Version	4.0
Revision date	27th February 2024		

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

Substance / mixture	TOTAL PROTEIN_R1
Number	mixture
UFI	BLT00054, BLT00055, XSYS0018
Other mixture names	ARHK-VJ1C-KE7U-9PC4
	TP 250, TP 500, TP 440

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

Reagent 1 is a part of diagnostic kit TOTAL PROTEIN for quantitative in vitro determination of Total Protein in human serum, plasma and urine.

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

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 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.

Skin Corr. 1B, H314

Eye Dam. 1, H318

Aquatic Chronic 3, H412

Most serious adverse physico-chemical effects

Unknown

Most serious adverse effects on human health and the environment

May cause an allergic skin reaction. May cause allergy or asthma symptoms or breathing difficulties if inhaled. Causes severe skin burns and eye damage. Harmful to aquatic life with long lasting effects.

TOTAL PROTEIN_R1

Creation date	19th September 2016	Version	4.0
Revision date	27th February 2024		

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

Danger

Hazardous substances

sodium hydroxide

Hazard statements

H314

Causes severe skin burns and eye damage.

H412

Harmful to aquatic life with long lasting effects.

Precautionary statements

P260

Do not breathe vapours.

P280

Wear protective gloves/protective clothing/eye protection/face protection.

P301+P330+P331

IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.

P303+P361+P353

IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower.

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.

SECTION 3: Composition/information on ingredients**3.2. Mixtures****Chemical characterization**

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
Index: 011-002-00-6 CAS: 1310-73-2 EC: 215-185-5 Registration number: 01-2119457892-27-0000	sodium hydroxide	2,4	Met. Corr. 1, H290 Skin Corr. 1A, H314 Eye Dam. 1, H318 Specific concentration limit: Skin Corr. 1B, H314: 2 % ≤ C < 5 % Skin Corr. 1A, H314: C ≥ 5 % Eye Irrit. 2, H319: 0.5 % ≤ C < 2 % Skin Irrit. 2, H315: 0.5 % ≤ C < 2 %	
CAS: 7681-11-0 EC: 231-659-4 Registration number: 01-2119966161-40-xxxx	Potassium iodide	0,5	STOT RE 1, H372 (thyroid gland, gastrointestinal system (orally))	

TOTAL PROTEIN_R1

Creation date 19th September 2016

Revision date 27th February 2024

Version

4.0

Identification numbers	Substance name	Content in % weight	Classification according to Regulation (EC) No 1272/2008	Note
Index: 029-023-00-4 CAS: 7758-99-8 EC: 231-847-6	copper sulphate pentahydrate	0,3	Acute Tox. 4, H302 Eye Dam. 1, H318 Aquatic Acute 1, H400 (M=10) Aquatic Chronic 1, H410 (M=1) Specific concentration limit: ATE Oral = 481 mg/kg bw	

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

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

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

If on skin

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

If in eyes

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

If swallowed

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

If inhaled

Possible respiratory tract irritation, cough, asthma, headache.

If on skin

Possible sensitizing effect. Possible skin burns.

If in eyes

Irritation or inflammation. Risk of blindness.

If swallowed

Irritation of GIT, nausea.

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

Use suitable extinguishing media according burning substances of surroundings.

Unsuitable extinguishing media

Unknown.

5.2. Special hazards arising from the substance or mixture

Fire may cause evolution of hydrogen iodide.

5.3. Advice for firefighters

Use breathing apparatus. Wear protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

The mixture is non-flammable. Provide sufficient ventilation. Follow the instructions in Sections 7 and 8.

TOTAL PROTEIN_R1

Creation date	19th September 2016	Version	4.0
Revision date	27th February 2024		

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 Section 13. Collected material should be disposed of in accordance with locally valid regulations.

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 principles of work in laboratory. Observe the normal operating procedures for handling chemical substances and mixtures. Do not eat, drink or 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 8 °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**

The mixture contains substances for which occupational exposure limits are set.

8.2. Exposure controls

Observe the usual occupational health measures, especially good ventilation.

Eye/face protection

Protective goggles.

Skin protection

Hand protection: Product resistant protective gloves. Protective clothing.

Respiratory protection

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	blue
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	>13 (undiluted at 20 °C)
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

TOTAL PROTEIN_R1

Creation date	19th September 2016	Version	4.0
Revision date	27th February 2024		

Particle characteristics

data not available

Form

clear

9.2. Other information

not available

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

The mixture is non-flammable.

10.2. Chemical stability

Sensitivity to light.

10.3. Possibility of hazardous reactions

The product is stable under normal conditions.

10.4. Conditions to avoid

Avoid exposure to sunlight.

10.5. Incompatible materials

Metals, strong oxidizing agents and strong acids, ammonia, hydrogen peroxide, fluorine.

10.6. Hazardous decomposition products

Hydrogen at contact with metals.

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 the available data, the criteria for classification of the mixture are not met.

TOTAL PROTEIN_R1						
Route of exposure	Parameter	Value	Exposure time	Species	Sex	Value determination
Oral	ATE	165900 mg/kg				Calculation of value

copper sulphate pentahydrate						
Route of exposure	Parameter	Value	Exposure time	Species	Sex	Value determination
Oral	LD ₅₀	482 mg/kg		Rat		
Dermal	LD ₅₀	>2000 mg/kg		Rat		
Oral	ATE	481 mg/kg bw				

Potassium iodide						
Route of exposure	Parameter	Value	Exposure time	Species	Sex	Value determination
Oral	LD ₅₀	1962 mg/kg		Mouse		
Oral	LDLo	2779 mg/kg		Rat		
Dermal		3160 mg/kg		Rabbit		

sodium hydroxide						
Route of exposure	Parameter	Value	Exposure time	Species	Sex	Value determination
Oral	LD ₅₀	325 mg/kg		Rat		
Dermal	LD ₅₀	1350 mg/kg		Rabbit		
Oral	LD ₅₀	500 mg/kg		Rabbit		
Dermal	LD ₅₀	40 mg/kg		Mouse		

TOTAL PROTEIN_R1

Creation date	19th September 2016	Version	4.0
Revision date	27th February 2024		

Skin corrosion/irritation

Causes severe skin burns and eye damage. Data for the components of the mixture are not available.

Serious eye damage/irritation

Causes severe skin burns and eye damage. Causes serious eye damage. 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

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.

Acute toxicity

Potassium iodide				
Parameter	Value	Exposure time	Species	Environment
EC ₅₀	2.4 mg/l	48 hours	Daphnia (Daphnia magna)	
LC ₅₀	896 mg/l	96 hours	Fish (Oncorhynchus mykiss)	

sodium hydroxide				
Parameter	Value	Exposure time	Species	Environment
EC ₅₀	76 mg/l	24 hours	Daphnia (Daphnia magna)	

TOTAL PROTEIN_R1

Creation date	19th September 2016	Version	4.0
Revision date	27th February 2024		

sodium hydroxide				
Parameter	Value	Exposure time	Species	Environment
EC ₅₀	145 mg/l	24 hours	Fish (Poecilia reticulata)	
EC ₅₀	40.4 mg/l	48 hours	Daphnia (Daphnia magna)	
LC ₅₀	160 mg/l	24 hours	Fish (Carassius auratus)	

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

The product is soluble and mobile in water and soil.

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

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.

TOTAL PROTEIN_R1

Creation date	19th September 2016	Version	4.0
Revision date	27th February 2024		

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**

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.
H372	Causes damage to thyroid gland, the gastro-intestinal system (oral) 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.

Guidelines for safe handling used in the safety data sheet

P260	Do not breathe vapours.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P301+P330+P331	IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.
P303+P361+P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower.
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

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

TOTAL PROTEIN_R1

Creation date	19th September 2016	Version	4.0
Revision date	27th February 2024		

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 K _{ow}	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 Dam.	Serious eye damage
Met. Corr.	Corrosive to metals
Skin Corr.	Skin corrosion
STOT RE	Specific target organ toxicity - repeated 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

Designed for professional 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 4.0 replaces the SDS version from 26 April 2021. Changes were made in sections 2, 11, 12, 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.