

UIBC_R1

Creation date	23rd March 2015	Version	3.0
Revision date	15th August 2023		

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

Substance / mixture	UIBC_R1
Number	mixture
Other mixture names	XSYS0050
	UIBC 125

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 UIBC for quantitative in vitro determination of unsaturated iron-binding capacity in serum and plasma.

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.
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	Czech Republic
Identification number (CRN)	26918846
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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 not classified as dangerous according to Regulation (EC) No 1272/2008.

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

2.2. Label elements**Supplemental information**

EUH208	Contains hydroxylamine hydrochloride. May produce an allergic reaction.
EUH210	Safety data sheet available on request.

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.

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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: 77-86-1 EC: 201-064-4	Tris(hydroxymethyl)aminomethane	<2,7	Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335	
Index: 612-123-00-2 CAS: 5470-11-1 EC: 226-798-2	hydroxylamine hydrochloride	<0,7	Met. Corr. 1, H290 Acute Tox. 4, H302, H312 Skin Irrit. 2, H315 Skin Sens. 1, H317 Eye Irrit. 2, H319 Carc. 2, H351 STOT RE 2, H373 Aquatic Acute 1, H400 (M=1)	
CAS: 144-55-8 EC: 205-633-8	sodium hydrogencarbonate	<0,3	not classified as dangerous	2
Index: 612-082-00-0 CAS: 62-56-6 EC: 200-543-5	thiourea	0,1	Acute Tox. 4, H302 Carc. 2, H351 Repr. 2, H361d Aquatic Chronic 2, H411	
CAS: 9002-93-1 EC: 618-344-0	2-[4-(2,4,4-trimethylpentan-2-yl)phenoxy] ethanol	<0,1	Acute Tox. 4, H302 Skin Irrit. 2, H315 Eye Dam. 1, H318 Aquatic Acute 1, H400 (M=1) Aquatic Chronic 1, H410	3, 4
Index: 016-020-00-8 CAS: 7664-93-9 EC: 231-639-5	sulphuric acid ... %	<0,01	Skin Corr. 1A, H314 Specific concentration limit: Skin Corr. 1A, H314: C ≥ 15 % Eye Irrit. 2, H319: 5 % ≤ C < 15 % Skin Irrit. 2, H315: 5 % ≤ C < 15 %	1, 2

Notes

- 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.
- A substance for which exposure limits are set.
- Substance of very high concern - SVHC.
- The substance is included in Annex XIV of the REACH Regulation

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.

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If on skin

Remove contaminated clothes. After contact with skin, wash immediately with soap and water.

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.

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

May produce an allergic reaction. May cause an allergic skin reaction.

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**

Accommodate extinguishing components to the location of fire.

Unsuitable extinguishing media

Unknown.

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 chemical resistant gloves. Use a self-contained breathing apparatus and full-body protective clothing.

SECTION 6: Accidental release measures**6.1. Personal precautions, protective equipment and emergency procedures**

Follow the instructions in the Sections 7 and 8. Do not inhale vapours. Avoid contact with skin and eyes. Observe the principles of work safety in chemical laboratories.

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

After removal of the product, wash the contaminated site with plenty of water.

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 concentrations exceeding the occupational exposure limits. Use personal protective equipment as per Section 8. Observe valid legal regulations on safety and health protection.

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)

For in vitro diagnostic devices.

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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
sodium hydrogencarbonate (CAS: 144-55-8)	PEL	5 mg/m ³		irritating to mucous membranes (eyes, respiratory system) and skin,
	NPK-P	10 mg/m ³		
sulphuric acid ... % (CAS: 7664-93-9)	PEL	1 mg/m ³		irritating to mucous membranes (eyes, respiratory system) and skin
	NPK-P	2 mg/m ³		
	PEL	0,05 mg/m ³		, irritating to mucous membranes (eyes, respiratory system) and skin

European Union**Commission Directive 2009/161/EU**

Substance name (component)	Type	Value
Sulphuric acid (mist) (CAS: 7664-93-9)	OEL 8 hours	0,05 mg/m ³

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. Follow the usual measures intended for health protection at work and especially for good ventilation.

Eye/face protection

Protective goggles.

Skin protection

When handling in long-term or repeatedly, use protective gloves.

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.

SECTION 9: Physical and chemical properties**9.1. Information on basic physical and chemical properties**

Physical state	liquid
Colour	orange to colorless clear solution
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

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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	8.4 (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
Particle characteristics	data not available
Form	clear solution

9.2. Other information

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.

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**

No toxicological data is available for the mixture.

Acute toxicity

Based on available data the classification criteria are not met.

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Route of exposure	Parameter	Value	Exposure time	Species	Sex	Value determination
Oral	ATE	62030 mg/kg				Calculation of value
Dermal	ATE	164200 mg/kg				Calculation of value

2-[4-(2,4,4-trimethylpentan-2-yl)phenoxy]ethanol						
Route of exposure	Parameter	Value	Exposure time	Species	Sex	Value determination
Oral	LD ₅₀	500 mg/kg		Rat		
Dermal	LD ₅₀	8000 mg/kg		Rabbit		

hydroxylamine hydrochloride						
Route of exposure	Parameter	Value	Exposure time	Species	Sex	Value determination
Oral	LD ₅₀	141 mg/kg		Rat (Rattus norvegicus)		

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sulphuric acid ... %						
Route of exposure	Parameter	Value	Exposure time	Species	Sex	Value determination
Oral	LD ₅₀	2140 mg/kg		Rat		
Inhalation	LC ₅₀	375 mg/m ³		Rat		

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

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. 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

Acute toxicity

2-[4-(2,4,4-trimethylpentan-2-yl)phenoxy]ethanol				
Parameter	Value	Exposure time	Species	Environment
LC ₅₀	8.9 mg/l	96 hours	Fish (Pimephales promelas)	
EC ₅₀	26 mg/l	48 hours	Daphnia (Daphnia magna)	

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hydroxylamine hydrochloride				
Parameter	Value	Exposure time	Species	Environment
LC ₅₀	1-10 mg/l	48 hours	Fish (Leuciscus idus)	

sulphuric acid ... %				
Parameter	Value	Exposure time	Species	Environment
EC ₅₀	>100 mg/l	48 hours	Daphnia (Daphnia magna)	
IC ₅₀	100 mg/l	72 hours	Algae (Selenastrum capricornutum)	
LC ₅₀	16-28 mg/l	96 hours	Fish	

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

not 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

16 05 06 laboratory chemicals, consisting of or containing hazardous substances, including mixtures of laboratory chemicals *

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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 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. Product contains regulated explosives precursor: Making available, introduction, possession and use of those precursors by member of the general public according to Regulation (EU) 2019/1148, Article 5 to 9. 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.
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.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
H351	Suspected of causing cancer.
H361d	Suspected of damaging the unborn child.
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.

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H411 Toxic to aquatic life with long lasting effects.

A list of additional standard phrases used in the safety data sheet

EUH208 Contains hydroxylamine hydrochloride. May produce an allergic reaction.

EUH210 Safety data sheet available on request.

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
IC ₅₀	Concentration causing 50% blockade
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)
Carc.	Carcinogenicity
Eye Dam.	Serious eye damage
Met. Corr.	Corrosive to metals

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Repr.	Reproductive toxicity
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

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 19 July 2021. Changes were made in sections 2, 11, 12, 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.