

XL MULTICAL

Creation date	07th December 2021	Version	2.0
Revision date	08th January 2024		

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

- 1.1. Product identifier**
 Substance / mixture XL MULTICAL mixture
 Number XSYS0034, XSYS0122
 Other mixture names
 XL MULTICAL 10x3
 XL MULTICAL 4x3
- 1.2. Relevant identified uses of the substance or mixture and uses advised against**
Mixture's intended use
 XL Multical is a lyophilized calibrator based on human serum. The concentrations and activities are suitable for calibration of clinical chemistry assays on automated clinical chemistry analyzers.
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 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 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. Dust may form explosive mixture with air.

SECTION 3: Composition/information on ingredients

- 3.2. Mixtures**
Chemical characterization
 Mixture of substances specified below. Handle as potentially infectious.
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: 9001-77-8 EC: 232-630-9	Phosphatase, acid	<0,1	Resp. Sens. 1, H334	

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Identification numbers	Substance name	Content in % weight	Classification according to Regulation (EC) No 1272/2008	Note
Index: 647-015-00-4 CAS: 9000-90-2 EC: 232-565-6	amylase, α-	<0,1	Resp. Sens. 1, H334	
CAS: 9001-62-1 EC: 232-619-9	Triacylglycerol lipase	<0,1	Resp. Sens. 1, H334	
CAS: 9046-27-9 EC: 232-931-5	Glutamyltransferase, γ-	<0,1	Skin Irrit. 2, H315 Eye Irrit. 2, H319 Resp. Sens. 1, H334 STOT SE 3, H335	

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.

If on skin

Remove contaminated clothes. If on skin, rinse well with 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 eye irritation persists, consult a specialist.

If swallowed

Keep respiratory tract clear. Do not give milk or alcoholic beverages. Never give anything by mouth to an unconscious person. 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

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

Accommodate extinguishing components to the location of fire.

Unsuitable extinguishing media

not available

5.2. Special hazards arising from the substance or mixture

Hazardous combustion products: Carbon oxides, Nitrogen oxides (NO_x), Sulphur oxides, Sodium oxides, Gaseous hydrogen chloride (HCl).

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.

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

Follow the instructions in the Sections 7 and 8. Avoid dust formation.

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

Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal. 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**

Use personal protective equipment as per Section 8. Observe valid legal regulations on safety and health protection. Smoking, eating and drinking should be prohibited in the application area. Provide appropriate exhaust ventilation at places where dust is formed. No decomposition if stored and applied as directed.

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. See label, package insert or internal guidelines. No materials to be especially mentioned.

Storage class

11 - Other combustible solids

Storage temperature

min 2 °C, max 8 °C

7.3. Specific end use(s)

Laboratory chemicals

SECTION 8: Exposure controls/personal protection**8.1. Control parameters**

The mixture contains substances for which occupational exposure limits are set. The mixture contains no 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.

In case of contact through splashing:

Material : Nitrile rubber

Break through time : > 30 min

Glove thickness : > 0,11 mm

In case of full contact:

Material : butyl-rubber

Break through time : > 480 min

Glove thickness : > 0,4 mm

Respiratory protection

No personal respiratory protective equipment normally required.

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	yellow
color intensity	light

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Odour	data not available
Melting point/freezing point	data not available
Boiling point or initial boiling point and boiling range	data not available
Flammability	Sustains combustion
Lower and upper explosion limit	data not available
Flash point	not applicable
Auto-ignition temperature	not applicable
Decomposition temperature	data not available
pH	6.7-7.2 (undiluted)
Kinematic viscosity	data not available
Solubility in water	soluble
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	data not available
Phosphatase, acid (CAS: 9001-77-8)	liquid
Phosphatase, acid (CAS: 9001-77-8)	solid: bulk
Triacylglycerol lipase (CAS: 9001-62-1)	liquid
Triacylglycerol lipase (CAS: 9001-62-1)	solid: bulk
Triacylglycerol lipase (CAS: 9001-62-1)	solid: particulate/powder

9.2. Other information

not available

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

No dangerous reaction known under conditions of normal use.

10.2. Chemical stability

The product is stable under normal conditions.

10.3. Possibility of hazardous reactions

Stable under recommended storage conditions. No hazards to be specially mentioned.

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 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

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

Glutamyltransferase, γ -					
Route of exposure	Parameter	Value	Exposure time	Species	Sex
Oral		5001 mg/kg			
Inhalation		30 mg/l			
Dermal		5001 mg/kg			

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Phosphatase, acid					
Route of exposure	Parameter	Value	Exposure time	Species	Sex
Oral		>5001 mg/kg			
Inhalation		>30 mg/l			
Dermal		>5001 mg/kg			

Triacylglycerol lipase					
Route of exposure	Parameter	Value	Exposure time	Species	Sex
Oral	LD ₅₀	2700 mg/kg		Rat	

Skin corrosion/irritation

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.

Serious eye damage/irritation

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.

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**

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

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Acute toxicity

Glutamyltransferase, γ -				
Parameter	Value	Exposure time	Species	Environment
LC ₅₀	100 mg/l			

Phosphatase, acid				
Parameter	Value	Exposure time	Species	Environment
	>100 mg/l	96 hours	Fish	

Triacylglycerol lipase				
Parameter	Value	Exposure time	Species	Environment
LC ₅₀	262.3 mg/l	96 hours	Fish (Oncorhynchus mykiss)	
EC ₅₀	262.3 mg/kg	48 hours	Daphnia (Daphnia magna)	
ErC ₅₀	15.5 mg/l	72 hours	Algae and other aquatic plants (Desmodesmus subspicatus)	

12.2. Persistence and degradability

Lipase, triacylglycerol: Biodegradability

Test Type: aerobic

Inoculum: activated sludge

Concentration: 10 mg/l

Result: Readily biodegradable.

Biodegradation: 88 %

Exposure time: 28 d

Method: OECD Test Guideline 301B

GLP: yes

Test Type: aerobic

Inoculum: activated sludge

Concentration: 250 mg/l

Result: Readily biodegradable.

Biodegradation: 99 %

Exposure time: 28 d

Method: OECD Test Guideline 301E

GLP: yes

12.3. Bioaccumulative potential

Lipase, triacylglycerol:

Partition coefficient: noctanol/water: log Pow: -1,93 (20 °C)

pH: 6,5 - 7

Method: OECD Test Guideline 107

GLP: yes

12.4. Mobility in soil

No data are available for either the mixture or the components.

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

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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.

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. 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**

H315	Causes skin irritation.
H319	Causes serious eye irritation.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H335	May cause respiratory irritation.

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.

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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 K _{ow}	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
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
Eye Irrit.	Eye irritation
Resp. Sens.	Respiratory sensitization
Skin Irrit.	Skin irritation
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.

The changes (which information has been added, deleted or modified)

The version 2.0 replaces the SDS version from 29 May 2023. Changes were made in sections 1, 2, 11, 15 and 16.

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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.