

AST-GOT_R1

Creation date	27th May 2015	Version	4.0
Revision date	29th November 2023		

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

- 1.1. Product identifier**
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Substance / mixture
mixture
Number
BLT00050, BLT00051, XSYS0016, XSYS0073
UFI
YMDf-7EN4-1H7J-XF4E
Other mixture names
AST/GOT 250, AST/GOT 500, AST/GOT 330, AST/GOT 564 XL-1000
- 1.2. Relevant identified uses of the substance or mixture and uses advised against**
Mixture's intended use
Diagnostic reagent for quantitative in vitro determination of AST/GOT (Aspartate Aminotransferase) in human serum and plasma.
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 Irrit. 2, H315
Eye Irrit. 2, H319
Most serious adverse physico-chemical effects
Unknown.
Most serious adverse effects on human health and the environment
Causes skin irritation. Causes serious eye irritation.

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2.2. Label elements

Hazard pictogram

**Signal word**

Warning

Hazardous substances

Aspartic acid
Tris(hydroxymethyl)aminomethane
sodium hydroxide

Hazard statements

H315 Causes skin irritation.
H319 Causes serious eye irritation.

Precautionary statements

P280 Wear protective gloves/protective clothing/eye protection.
P302+P352 IF ON SKIN: Wash with plenty of water and soap.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337+P313 If eye irritation persists: Get medical advice/attention.

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 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: 56-84-8 EC: 200-291-6	Aspartic acid	<4,5	Eye Irrit. 2, H319	
CAS: 77-86-1 EC: 201-064-4	Tris(hydroxymethyl)aminomethane	1,3	Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335	
Index: 011-002-00-6 CAS: 1310-73-2 EC: 215-185-5	sodium hydroxide	<0,5	Skin Corr. 1A, H314 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 %	1
Index: 011-004-00-7 CAS: 26628-22-8 EC: 247-852-1	sodium azide	<0,1	Acute Tox. 2, H300 Aquatic Acute 1, H400 (M=1) Aquatic Chronic 1, H410 (M=1) EUH032	1

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Identification numbers	Substance name	Content in % weight	Classification according to Regulation (EC) No 1272/2008	Note
CAS: 1403-66-3	Gentamicin	0,01	Repr. 1A, H360 STOT RE 1, H372 Aquatic Acute 1, H400 Aquatic Chronic 1, H410	

Notes

1 A substance for which exposure limits are set.

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**

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.

If inhaled

Terminate the exposure immediately; move the affected person to fresh air.

If on skin

Remove contaminated clothes. Wash the affected area with plenty of water, lukewarm if possible. Soap, soap solution or shampoo should be used if there is no skin injury. Provide medical treatment if skin irritation persists.

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. Rinsing should continue at least for 10 minutes. Provide medical treatment, specialized if possible.

If swallowed

Rinse out the mouth with water and provide 2-5 dL of water. Provide medical treatment if the person has any health problems.

4.2. Most important symptoms and effects, both acute and delayed**If inhaled**

Not expected.

If on skin

Causes skin irritation.

If in eyes

Causes serious eye irritation.

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**

The mixture is not flammable. The measures should be adapted to burning substances in the surrounding area.

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 a chemical protection suit only where personal (close) contact is likely. Use a self-contained breathing apparatus and full-body protective clothing. Do not allow run-off of contaminated fire extinguishing material to enter drains or surface and ground water.

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

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

6.2. Environmental precautions

Do not discharge into the drains, surface waters and groundwater.

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.

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

+2-+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.

Czech Republic**Government Regulation 330/2023 Coll.**

Substance name (component)	Type	Value	Note
sodium hydroxide (CAS: 1310-73-2)	PEL	1 mg/m ³	irritating to mucous membranes (eyes, respiratory system) and skin
	NPK-P	2 mg/m ³	
sodium azide (CAS: 26628-22-8)	PEL	0,1 mg/m ³	skin penetration is significantly involved during exposure, irritating to mucous membranes (eyes, respiratory system) and skin
	NPK-P	0,3 mg/m ³	

European Union**Commission Directive 2000/39/EC**

Substance name (component)	Type	Value	Note
sodium azide (CAS: 26628-22-8)	OEL 8 hours	0,1 mg/m ³	Skin
	OEL 15 minutes	0,3 mg/m ³	

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8.2. Exposure controls

Sufficient ventilation. Wash your hands thoroughly with water and soap after work and before breaks for a meal and rest.

Eye/face protection

Protective goggles.

Skin protection

Hand protection: Protective gloves - rubber, resistant against the product. Protective clothing.

Respiratory protection

Not required with adequate ventilation.

Thermal hazard

Not available.

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**

Physical state	liquid
Colour	colourless
Odour	without fragrance
Melting point/freezing point	data not available
Boiling point or initial boiling point and boiling range	data not available
Flammability	The product is non-flammable.
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	7.85-8 (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 colourless liquid.

9.2. Other information

Oxidising properties	The product has no oxidizing properties.
Explosive properties	The product does not have explosive properties.

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

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

10.2. Chemical stability

The mixture is stable at normal temperature and pressure.

10.3. Possibility of hazardous reactions

Unknown.

10.4. Conditions to avoid

Avoid exposure to heat and solar radiation.

10.5. Incompatible materials

Metals. Ammonia. Protect against strong acids, strong oxidizing agents.

10.6. Hazardous decomposition products

It releases hydrogen in contact with metals.

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SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

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. 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.

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Route of exposure	Parameter	Value	Exposure time	Species	Sex	Value determination
Oral	ATE	28420 mg/kg				Calculation of value

sodium azide						
Route of exposure	Parameter	Value	Exposure time	Species	Sex	Value determination
Oral	LD ₅₀	27 mg/kg bw				
Inhalation	LC ₅₀	54 mg/m ³	4 hours	Rat		

Skin corrosion/irritation

Causes skin irritation. Data for the components of the mixture are not available.

Serious eye damage/irritation

Causes serious eye irritation. 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.

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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.

Acute toxicity

sodium azide				
Parameter	Value	Exposure time	Species	Environment
LC ₅₀	680 µg/l		Fish	Fresh water
EC ₅₀ /LC ₅₀	400 µg/l		Invertebrates	Fresh water
EC ₅₀ /LC ₅₀	150 µg/l		Invertebrates	Salt water
EC ₅₀ /LC ₅₀	348 µg/l		Algae	Fresh water
EC ₅₀ /LC ₅₀	5.6 mg/l		Microorganisms	
NOEC	30 µg/l		Microorganisms	

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 (<i>Selenastrum capricornutum</i>)	Fresh water

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

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**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.

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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.

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

The mixture is not hazardous to the environment during transport.

14.6. Special precautions for user

Reference in the Sections 4 to 8.

14.7. Maritime transport in bulk according to IMO instruments

Not transported.

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**

H300	Fatal if swallowed.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
H360	May damage fertility or the unborn child.
H372	Causes damage to organs through prolonged or repeated exposure.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.

Guidelines for safe handling used in the safety data sheet

P280 Wear protective gloves/protective clothing/eye protection.

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P302+P352 IF ON SKIN: Wash with plenty of water and soap.
 P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 P337+P313 If eye irritation persists: Get medical advice/attention.

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

EUH032 Contact with acids liberates very toxic gas.

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 K _{ow}	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)
Repr.	Reproductive toxicity
Skin Corr.	Skin corrosion

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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.

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

The version 4.0 replaces the SDS version from 12 April 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.