

HOMOCYSTEINE 2R 100_R1

Creation date	17th April 2020	Version	2.0
Revision date	13th June 2024		

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

HOMOCYSTEINE 2R 100_R1

Substance / mixture

mixture

Number

50003526

Other mixture names

HOMOCYSTEINE 2R 100

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

The homocysteine control kit is intended for the enzymatic determination of homocysteine in human serum and plasma from Axis-Shield.

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

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**Distributor**

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

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msds@erba.com

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www.erbalachema.com

Manufacturer

Name or trade name

Axis-Shield Diagnostics Ltd

Address

Luna Place, Technology Park, Dundee, DD2 1XA

United Kingdom

Phone

01382422000

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.

Flam. Liq. 3, H226

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

Warning

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Hazard statements

H226 Flammable liquid and vapour.

Precautionary statements

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

P233 Keep container tightly closed.

P240 Ground and bond container and receiving equipment.

P241 Use explosion-proof electrical/ventilating/lighting equipment.

P242 Use non-sparking tools.

P243 Take action to prevent static discharges.

P273 Avoid release to the environment.

P280 Wear protective gloves/protective clothing/face protection.

P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.

P370+P378 In case of fire: Use carbon dioxide to extinguish.

P403+P235 Store in a well-ventilated place. Keep cool.

P501 Dispose of contents/container to according to applicable regulations.

Supplemental information

EUH032 Contact with acids liberates very toxic gas.

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
Index: 603-002-00-5 CAS: 64-17-5 EC: 200-578-6	ethanol	<3,5	Flam. Liq. 2, H225	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

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**

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

Remove casualty from exposure ensuring one's own safety whilst doing so. Seek medical attention. Provide medical treatment.

If on skin

Wash immediately with plenty of 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.

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If swallowed

Rinse out the mouth with clean water. In the event of issues, find medical help. Do NOT induce vomiting.

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

Not expected.

If on skin

There may be mild irritation at the site of contact.

If in eyes

There may be irritation and redness.

If swallowed

There may be irritation of the throat.

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**

Suitable extinguishing media for the surrounding fire should be used. Use water spray to cool containers.

Unsuitable extinguishing media

not available

5.2. Special hazards arising from the substance or mixture

In combustion emits toxic fumes.

5.3. Advice for firefighters

Wear self-contained breathing apparatus. Wear protective clothing to prevent contact with skin and eyes.

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

Refer to section 8 of SDS for personal protection details. Turn leaking containers leakside up to prevent the escape of liquid. Mark out the contaminated area with signs and prevent access to unauthorised personnel.

6.2. Environmental precautions

Prevent contamination of the soil and entering surface or ground water. Do not allow to enter drains. Do not discharge into drains or rivers. Contain the spillage using bunding.

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 the Section 13. Dispose of the collected material according to the instructions in the 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**

Avoid the formation or spread of mists in the air. Avoid direct contact with the substance.

7.2. Conditions for safe storage, including any incompatibilities

Keep container tightly closed. The floor of the storage room must be impermeable to prevent the escape of liquids. Keep only in original packaging.

Storage temperature min 2 °C, max 8 °C

The specific requirements or rules relating to the substance/mixture

No data available.

7.3. Specific end use(s)

For professional use only.

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

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Czech Republic

Government Regulation 330/2023 Coll.

Substance name (component)	Type	Value	Note
ethanol (CAS: 64-17-5)	PEL	1000 mg/m ³	
	PEL	522 ppm	
	NPK-P	3000 mg/m ³	
	NPK-P	1566 ppm	
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	

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

Safety glasses.

Skin protection

Hand protection: Protective gloves resistant to the product. Contaminated skin should be washed thoroughly.

Respiratory protection

Not required.

Thermal hazard

not available

Environmental exposure controls

Observe usual measures for protection of the environment, see Section 6.2.

More information

The floor of the storage room must be impermeable to prevent the escape of liquids.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	liquid
Colour	colourless
Odour	odourless
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	60-93 °C
Auto-ignition temperature	data not available
Decomposition temperature	data not available
pH	8.5 (undiluted at 20 °C)
Kinematic viscosity	data not available

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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	
Density	data not available
Relative density	1.005
Relative vapour density	data not available
Particle characteristics	data not available
No data available.	

9.2. Other information

Appearance	Colourless liquid
Oxidising properties	The product has no oxidizing properties.
Explosive properties	The product does not have explosive properties.
No data available.	

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

Stable under recommended transport or storage conditions.

10.2. Chemical stability

The product is stable under normal conditions.

10.3. Possibility of hazardous reactions

The product is stable under normal conditions. Decomposition products may be formed due to heat.

10.4. Conditions to avoid

Keep away from heat.

10.5. Incompatible materials

Keep away from strong acids and oxidizing agents.

10.6. Hazardous decomposition products

In combustion emits toxic fumes.

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.

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

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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.

More information

Skin contact: There may be mild irritation at the site of contact.

Eye contact: There may be irritation and redness.

Ingestion: There may be irritation of the throat.

Delayed / immediate effects: Immediate effects can be expected after short-term exposure.

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	

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.

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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 06* chemicals consisting of or containing 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. 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**

H225 Highly flammable liquid and vapour.

H226 Flammable liquid and vapour.

H300 Fatal if swallowed.

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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	
P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P233	Keep container tightly closed.
P240	Ground and bond container and receiving equipment.
P241	Use explosion-proof electrical/ventilating/lighting equipment.
P242	Use non-sparking tools.
P243	Take action to prevent static discharges.
P273	Avoid release to the environment.
P280	Wear protective gloves/protective clothing/face protection.
P303+P361+P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.
P370+P378	In case of fire: Use carbon dioxide to extinguish.
P403+P235	Store in a well-ventilated place. Keep cool.
P501	Dispose of contents/container to according to applicable regulations.

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
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

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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)
Flam. Liq.	Flammable liquid

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 17 April 2020. Changes were made in sections 1, 2, 11, 12, 15 and 16.

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.