SAFETY DATA SHEET

according to Commission Regulation (EU) 2020/878 as amended

Hb-Vario Reagent B

Creation date	07th June 2022		
Revision date	03rd June 2024	Version	2.0

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

1.1. Product identifier — Hb-Vario Reagent B

Substance / mixture	mixture
Number	REG00038
Other mixture names	
Hb- Vario Kit, Činidlo B, Reagent B	

1.2. Relevant identified uses of the substance or mixture and uses advised against

Mixture's intended use

The Hb-Vario Kit is intended for the in vitro quantitative determination of glycated human hemoglobin, referred to as Hemoglobin A1c or HbA1c. (IFCC mmol/mol and NGSP %) in human blood using ion-exchange high performance liquid chromatography (HPLC) on the Hb-Vario™ automated hemoglobin testing system (Hb-Vario™ Analyser). Hemoglobin A1c measurements are used as an aid in diagnosis of diabetes mellitus, as an aid to identify patients who may be at risk for developing diabetes mellitus, and for the monitoring of long- term blood glucose control in individuals with diabetes mellitus. The Hb-Vario Kit and Hb-Vario™ automated hemoglobin testing system (Hb-Vario™ Analyser) are intended for Professional Use Only.

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 then 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.

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: 011-004-00-7 CAS: 26628-22-8 EC: 247-852-1	sodium azide	0,02	Acute Tox. 2, H300 Aquatic Acute 1, H400 (M=1) Aquatic Chronic 1, H410 (M=1) EUH032	2
Index: 613-167-00-5 CAS: 55965-84-9	reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-2H-isothiazol-3-one	<0,001	Acute Tox. 3, H301 Acute Tox. 2, H310+H330 Skin Corr. 1C, H314 Skin Sens. 1A, H317 Eye Dam. 1, H318 Aquatic Acute 1, H400 (M=100) Aquatic Chronic 1, H410 (M=100) EUH071 Specific concentration limit: Eye Irrit. 2, H319: 0.06 % ≤ C < 0.6 % Skin Sens. 1A, H317: C ≥ 0.0015 % Skin Irrit. 2, H315: 0.06 % ≤ C < 0.6 % Skin Corr. 1C, H314: C ≥ 0.6 % Eye Dam. 1, H318: C ≥ 0.6 %	1

Notes

1 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.

2 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

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

If on skin

Remove contaminated clothes.

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 cause skin irritation.

If in eyes

Not expected.

If swallowed

Irritation, 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

Accommodate extinguishing components to the location of fire.

Unsuitable extinguishing media

not available

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. 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.

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 azide (CAS: 26628-22-8)	PEL	0,1 mg/m³	skin penetration is significantly involved during exposure, irritating to mucous membranes (eyes, respiratory system) and skin
	NPK-P	0,3 mg/m³	

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/m³	Skin
	OEL 15 minutes	0,3 mg/m³	

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.

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	colourless
Odour	data not available
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	6.5 (undiluted at 25 °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

9.2. Other information

Oxidising properties	It is not oxidising.
Explosive properties	The product does not have explosive properties.

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. 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. Dangerous outcomes such as carbon monoxide and carbon dioxide are formed at high temperature and in fire.

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 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/m³	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.

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
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

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
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.

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

H300	Fatal if swallowed.
H301	Toxic if swallowed.
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.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
H310+H330	Fatal in contact with skin or if inhaled.

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

EUH032	Contact with acids liberates very toxic gas.
EUH071	Corrosive to the respiratory tract.

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 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)
Eye Dam.	Serious eye damage
Skin Corr.	Skin corrosion
Skin Sens.	Skin sensitization

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 07 June 2022. Changes were made in sections 2, 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.