

GLUCOSE_R1

Creation date	14th January 2015	Version	4.0
Revision date	08th December 2023		

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

- 1.1. Product identifier**
Substance / mixture GLUCOSE_R1
Number mixture
UFI BLT00025, BLT00026, BLT00027, XSYS0012, XSYS0069
Other mixture names WY5U-AJ46-VE76-OWED
GLU 500; GLU 4x 250; GLU 1000; GLU 440; GLU 576 XL - 1000
- 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 for quantitative in vitro determination of Glucose in human serum, plasma and urine.
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.
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

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

Most serious adverse effects on human health and the environment

Causes serious eye irritation. Causes skin irritation.

- 2.2. Label elements**
Hazard pictogram



Signal word
Warning

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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.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

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 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: 011-002-00-6 CAS: 1310-73-2 EC: 215-185-5 Registration number: 01-2119457892-27-0000	sodium hydroxide	<0,75	Met. Corr. 1, H290 Skin Corr. 1A, H314 Eye Dam. 1, H318 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
CAS: 6381-92-6 EC: 205-358-3	chelaton III	<0,2	Acute Tox. 4, H332 STOT RE 2, H373	
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
Index: 604-001-00-2 CAS: 108-95-2 EC: 203-632-7	phenol	<0,1	Acute Tox. 3, H301+H311+H331 Skin Corr. 1B, H314 Muta. 2, H341 STOT RE 2 (**), H373 Specific concentration limit: Skin Irrit. 2, H315: 1 % ≤ C < 3 % Eye Irrit. 2, H319: 1 % ≤ C < 3 % Skin Corr. 1B, H314: C ≥ 3 %	1, 2
CAS: 9001-37-0 EC: 232-601-0	Glucose Oxidase	<0,03	Resp. Sens. 1, H334	
CAS: 83-07-8 EC: 201-452-3	4-Aminoantipyrine	0,01	Acute Tox. 4, H302 Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335	

Notes

** another exposure route cannot be ruled out

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- 1 A substance for which exposure limits are set.
- 2 Substance for which biological limit values exist.

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

Discontinue the exposure, remove casualty to fresh air, keep at rest and seek medical advice.

If on skin

After contact with skin, wash immediately with soap and water.

If in eyes

Rinse an open eye (hold eyelids with fingers) with plenty of water for about 15 minutes, transfer casualty to a specialist.

If swallowed

Rinse mouth with water, drink 1/2 of lukewarm water, seek medical attention immediately, and do not induce vomiting.

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

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**

Alcohol-resistant foam, carbon dioxide, powder, water spray jet, water mist. The extinguishing agents should be adapted to burning substances in the surrounding area.

Unsuitable extinguishing media

No unsuitable extinguishing media are known.

5.2. Special hazards arising from the substance or mixture

None.

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.

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.

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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. Observe the principles of work in laboratory. 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 min 2 °C, max 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****Czech Republic****Government Regulation 195/2021 Coll.**

Substance name (component)	Type	Value	Conversion for ppm	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	0,370	skin penetration is significantly involved during exposure, irritating to mucous membranes (eyes, respiratory system) and skin
	NPK-P	0,3 mg/m ³	0,370	
phenol (CAS: 108-95-2)	PEL	7,5 mg/m ³	0,256	skin penetration is significantly involved during exposure, irritating to mucous membranes (eyes, respiratory system) and skin
	NPK-P	15 mg/m ³	0,256	

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

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European Union

Commission Directive 2000/39/EC

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

European Union

Commission Directive 2009/161/EU

Substance name (component)	Type	Value	Note
phenol (CAS: 108-95-2)	OEL 8 hours	8 mg/m ³	Skin
	OEL 8 hours	2 ppm	
	OEL 15 minutes	16 mg/m ³	
	OEL 15 minutes	4 ppm	

Biological limit values

Czech Republic

Decree No. 107/2017 Coll.

Name	Parameter	Value	Tested material	Time of sampling
phenol (CAS: 108-95-2)	Phenol	300 mg/g of creatinine	Urine	End of shift
		360 µmol/mmol creatinine		

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

Protective goggles.

Skin protection

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

Respiratory protection

If all workplace limits are observed and good ventilation is ensured, no special precautions necessary.

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	yellow
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
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	7.15 (undiluted at 20 °C)

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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
Density 1.01 g/cm³ at 25 °C
Relative vapour density data not available
Particle characteristics data not available
Form clear

9.2. Other information

not available

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

Data 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. Avoid exposure to heat and solar radiation.

10.5. Incompatible materials

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

10.6. Hazardous decomposition products

Nitrogen oxides.

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	42410 mg/kg				Calculation of value
Dermal	ATE	600000 mg/kg				Calculation of value
Inhalation (vapor)	ATE	2870 mg/l				Calculation of value

4-Aminoantipyrine						
Route of exposure	Parameter	Value	Exposure time	Species	Sex	Value determination
Oral	LD ₅₀	1700 mg/kg		Rat		

Glucose Oxidase						
Route of exposure	Parameter	Value	Exposure time	Species	Sex	Value determination
Intraperitoneally	LD ₅₀	3 mg/kg		Mouse		

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chelaton III

Route of exposure	Parameter	Value	Exposure time	Species	Sex	Value determination
Oral	LD ₅₀	2800 mg/kg		Rat		
Inhalation	LC ₅₀	1000-5000 mg/m ³	4 hours	Rat		

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		

sodium hydroxide

Route of exposure	Parameter	Value	Exposure time	Species	Sex	Value determination
Oral	LD ₅₀	325 mg/kg		Rat		
Dermal	LD ₅₀	1350 mg/kg		Rabbit		
Oral	LD ₅₀	500 mg/kg		Rabbit		
Dermal	LD ₅₀	40 mg/kg		Mouse		

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

chelaton III				
Parameter	Value	Exposure time	Species	Environment
EC ₅₀	140 mg/l	48 hours	Daphnia (Daphnia magna)	
LC ₅₀	320 mg/l	96 hours	Fish (Poecilia reticulata)	
EC ₅₀	56 mg/l	8 hours	Bacteria (Pseudomonas putida)	
NOEC	25.7 mg/l	35 days	Fish (Branchydanio rerio)	
NOEC	25 mg/l	21 days	Daphnia (Daphnia magna)	

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	

sodium hydroxide				
Parameter	Value	Exposure time	Species	Environment
EC ₅₀	76 mg/l	24 hours	Daphnia (Daphnia magna)	
EC ₅₀	145 mg/l	24 hours	Fish (Poecilia reticulata)	
EC ₅₀	40.4 mg/l	48 hours	Daphnia (Daphnia magna)	
LC ₅₀	160 mg/l	24 hours	Fish (Carassius auratus)	

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

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

No data available.

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**

H290 May be corrosive to metals.

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H300	Fatal if swallowed.
H302	Harmful if swallowed.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H332	Harmful if inhaled.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H335	May cause respiratory irritation.
H341	Suspected of causing genetic defects.
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.
H301+H311+H331	Toxic if swallowed, in contact with skin or if inhaled.

Guidelines for safe handling used in the safety data sheet

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

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

EUH032	Contact with acids liberates very toxic gas.
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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

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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
Met. Corr.	Corrosive to metals
Muta.	Germ cell mutagenicity
Resp. Sens.	Respiratory sensitization
Skin Corr.	Skin corrosion
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

This compound is designed for professional use. It should not be used for purposes other than those described in Section 1.2.

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 16 June 2021. Changes were made in sections 2, 11, 12, 13, 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.