GLUCOSE HK_R2

Creation date	05th December 2019		
Revision date	13th February 2024	Version	3.0

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

1.1. Product identifier — GLUCOSE HK_R2

Substance / mixture	mixture
Number	XSYS0095
Other mixture names	
GLU HK	

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 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

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.

Most serious adverse effects on human health and the environment

Under normal conditions of use, the mixture does not cause adverse effects to humans and to the environment.

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

Aqueous solution containing organic and inorganic substances.

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: 017-002-01-X CAS: 7647-01-0 EC: 231-595-7 Registration number: 01-2119484862-27-XXXX	Hydrochloric acid	0,1-1	Met. Corr. 1, H290 Skin Corr. 1B, H314 STOT SE 3, H335 Specific concentration limit: Skin Irrit. 2, H315; Eye Irrit. 2, H319: 10 % ≤ C < 25 % STOT SE 3, H335: C ≥ 10 % Skin Corr. 1B, H314: C ≥ 25 %	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

If breathed in, move person into fresh air. Call a doctor if you feel unwell.

If on skin

Remove contaminated clothes. Wash affected area with soap or mild detergent and plenty of water until the removal of the mixture.

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

If swallowed rinse mouth with plenty of water provided person is conscious. Do not induce vomiting. Call a doctor if you feel unwell.

4.2. Most important symptoms and effects, both acute and delayed

If inhaled

May cause irritation.

If on skin

May cause skin irritation.

If in eyes

May cause severe irritation.

If swallowed

It can be harmful.

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

Water spray or regular foam, CO2, dry powder.

Unsuitable extinguishing media

not available

5.2. Special hazards arising from the substance or mixture

Thermal decomposition or combustion may generate toxic and hazardous fumes.

5.3. Advice for firefighters

Equipment for self-protection:
Wear self-contained breathing apparatus, flame and chemical resistant clothing, boots and gloves. Equipment must be conformed with EN criteria and used in highest condition of protection on the basis of the information reported in the previous sub-sections.
Further advices:
Water jets can be used successfully to cool containers exposed to the fire and disperse fumes.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Follow the instructions in the Sections 7 and 8. Remove the ignition and heat sources, provide sufficient ventilation and evacuate the area. Respiratory protection: is not required. Where risk assessment shows air-purifying respirators are appropriate, use masks with approved filter. Wear suitable protective clothing, rubber or polythene gloves, rubber shoes, safety glasses.

6.2. Environmental precautions

Rinse with plenty of water after collecting the product. Do not let the product enter drainage system, surface and ground-water or soil. Contact local authorities in case of environmental release. Do not empty into drains.

6.3. Methods and material for containment and cleaning up

Collect spilled material in containers. Where appropriate, moisten to prevent the dispersion of dust, absorb with inert materials and wash the area with plenty of water. Ensure adequate ventilation. Dispose of the contaminated material according to 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

Handle in a well ventilated place, and away from ignition sources, heat or flames. Avoid contact with incompatible materials. Keep the mixture away from drains, surface or ground waters. Do not eat, drink and smoke in the working areas. Wash hands with soap and water after handling the mixture. Remove contaminated clothing and protective equipment before entering dining areas.

7.2. Conditions for safe storage, including any incompatibilities

Store in a well-ventilated place. Store the product away from light and heat sources.Keep containers tightly closed and labelled with the name of the product. Avoid environmental release. Keep away from food and drinks. Keep away from contamination with heavy metals.

Storage temperature min 2 °C, max 8 °C

7.3. Specific end use(s)

Product for in vitro use only, intended for skilled professional users. Use the product in accordance with the Good Laboratory Practice.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

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

Substance name (component)	Type	Value	Note
Hydrochloric acid (CAS: 7647-01-0)	PEL	8 mg/m³	irritating to mucous membranes (eyes, respiratory system) and skin
	PEL	5 ppm	
	NPK-P	15 mg/m³	
	NPK-P	10 ppm	

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

Substance name (component)	Type	Value	Note
Hydrochloric acid (CAS: 7647-01-0)	OEL 8 hours	8 mg/m³	
	OEL 8 hours	5 ppm	
	OEL 15 minutes	15 mg/m³	
	OEL 15 minutes	10 ppm	

DNEL

Hydrochloric acid					
Workers / consumers	Route of exposure	Value	Effect	Value determination	Source
Workers	Inhalation	8.0 mg/m³	Chronic effects systemic		
Workers	Inhalation	15.0 mg/m³	Acute effects systemic		
Consumers	Inhalation	8.0 mg/m³	Chronic effects systemic		
Consumers	Inhalation	15.0 mg/m³	Acute effects systemic		

8.2. Exposure controls

Protective equipment resistant to chemicals. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Eye/face protection

Safety glasses. Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Skin protection

Handle with rubber or polyethylene gloves. Gloves must be inspected prior to use. Use proper gloves removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and Good Laboratory Practices. Wash and dry hands. The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it. Protective equipment resistant to chemicals. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Respiratory protection

If all workplace limits are observed and good ventilation is ensured, no special precautions necessary. It is not needed.

Thermal hazard

Not available.

Environmental exposure controls

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

More information

Appropriate risk management measures, that must be adopted at the workplace, have to be selected and applied, following the risks assessment carried out by the employer, in connection with his working activity (in according with Directive 98/24/EC and its subsequent amendments and additions).
If the results of this evaluation show that the general and collective prevention measures are not sufficient to reduce the risk, and if you can not prevent exposure to the mixture by other means, adequate personal protective equipments must be adopted, complying with the relevant technical EN standards.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	liquid
Colour	Colorless
Odour	Odorless
Melting point/freezing point	0 °C
Boiling point or initial boiling point and boiling range	>90 °C

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	7.7 (undiluted)
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	1.00502 g/cm³
Relative vapour density	data not available
Particle characteristics	data not available
Form	Colorless aqueous solution

9.2. Other information

Explosive properties: The product does not have explosive properties.

SECTION 10: Stability and reactivity

10.1. Reactivity

This mixture is stable under the normal conditions of use.

10.2. Chemical stability

The product is stable until the expiration date shown on the box and on the labels when stored at 2-8°C.

10.3. Possibility of hazardous reactions

Under the normal conditions of storage and usage, hazardous reactions are not expected.

10.4. Conditions to avoid

Keep out from heat and light.

10.5. Incompatible materials

Strong oxidizing agents, acids, bases, heavy metals and their salts.

10.6. Hazardous decomposition products

Thermal decomposition or combustion may include toxic and hazardous fumes.

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

Hydrogen chloride
Acute oral toxicity:
Following oral administration, the hydrochloric acid often causes vomiting. The damaging effect is determined mainly by the concentration. High concentrations can cause serious damage resulting danger to life (glottis edema, perforation/stenosis of the esophagus and stomach) and other kardiovascular and respiratory disorders. The ingestion of 5 - 20 ml of 33% hydrochloric acid can be lethal. For very diluted acid, the risk is reduced. For concentrations of hydrochloric acid at 3.3% it was identified an oral LD50 of 238-277 mg/kg for rats.

Acute skin toxicity: LD50 > 5.01 mg/kg - Rabbit

Acute inhalation toxicity:
LC50 values found in tests on rodents following inhalation of the vapors of hydrochloric acid were 8.3 mg/l for 30 minutes and 16.5 mg/l for 5 min in rats and 3.2 mg/l for 30 min in mice. However, for humans has been found that short-term inhalation (500-1000 ppm of gas of hydrochloric acid) can cause glottic spasms or respiratory and cardiac arrest.

Skin corrosion/irritation

Tests carried out on human skin show that 4% hydrochloric acid aqueous solutions cause a mild irritation, 10% solutions are instead irritating to the skin. Tests on rabbits' skin revealed phenomena of corrosion for concentrations of hydrochloric acid at 17% (0.5 ml, 4 h). After 1 hour of contact with 37% solutions there are already serious damage from corrosion.

Serious eye damage/irritation

In tests on rabbits' eyes, 3.3% hydrochloric acid aqueous solutions (0.1 ml) cause mild irritation, 5% solutions (0.03 ml) give severe irritation and even slight corrosion. 10% solutions (0.1 ml) cause damage to the cornea that could cause permanent visual disturbances.

Respiratory or skin sensitisation

There are no data from manipulation in the workplace that could experimentally confirm a potential of skin sensitization. Even tests on volunteers and animal tests were negative.

Germ cell mutagenicity

The Ames test gave negative results. A positive result, that is considered to be an artifact due to the low pH, it was obtained in a test of chromosomal aberration using hamster ovary cells. The effects of the low pH on in vitro studies are not a problem in vivo since the level of protons is adjusted systemically.

Carcinogenicity

No pre-neoplastic or neoplastic nasal injury was observed in male rats during a study long 128 weeks consisting in inhalation of 10 ppm of hydrochloric acid (gas). No evidence of carcinogenicity was observed in other animal studies of administration by inhalation, orally and by skin. In humans, there was no association between exposure to hydrochloric acid and cancer.

Reproductive toxicity

There are no reported studies reliable regarding the toxicity for reproduction and development in animals after oral, dermal exposure/administration or inhalation of hydrochloric acid.

Toxicity for specific target organ - single exposure

Following exposure to acid vapors there is a severe irritation of the upper respiratory tract. The effects match those of hydrochloric acid gas because it immediately reacts with moisture in the air to form mists of hydrochloric acid. Considering the concentration of the acid hydrochloric acid in the air, specific limits dose-effect can be drawn: 2-3 ppm: still no irritation of the mucous membranes, but initial minor ailments; 5-7 ppm (7.6 - 10.6 mg/m^3): slight irritation of the mucous membranes; 17-22 ppm (about 26.5-33.5 mg/m^3): inrespirabile, difficulty in breathing even for short term exposure.
Based on studies carried out in the workplace has been detected an IDLH value (immediately dangerous to life or health) of 50 ppm.

Toxicity for specific target organ - repeated exposure

After repeated contact with skin, hydrochloric acid, even when diluted, may cause skin damage (redness, drying, fissures, dermatitis). The main effect following exposure to repeated inhalation is irritation of the respiratory tract. By professional experience, it is shown that long term inhalation exposure to vapors of hydrochloric acid may lead to increase the incidence of respiratory diseases (chronic bronchitis). In the old reports, chronic exposure (but apparently still tolerable) led not only to airway irritation, but also to the onset of gastrointestinal diseases and typical damage to the teeth linked to inhalation of acid. A study long 2 years on rats, by administering 10 ppm of hydrochloric acid, led to the hyperplasia of the larynx and trachea. From these results, it was estimated that at exposures up to 2 ppm (even in unfavorable conditions) no effects are expected. The NOAEL for systemic toxicity was determined to 20 ppm in rats and mice.

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. Inhalation of vapors can cause: burning sensation, cough, asthma, shortness of breath, spasm, inflammation and edema of the larynx, spasm, inflammation and edema of the bronchi, pneumonia and pulmonary edema.

More information

The health effects of the product have not been thoroughly investigated. Data on toxicological effects of the hazardous ingredients are provided below.

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

It is accepted that the aquatic toxicity of hydrochloric acid results if sufficient acid is present to produce a very low pH (i.e. pH 3-5). Given that the environmental exposure assessment shows insignificant perturbation of aquatic pH levels from the formulation of the product and its proposed use, it is considered that there is no long-term risk to aquatic organisms and therefore chronic fish and invertebrate effects data are not required.

Acute toxicity

Hydrochloric acid				
Parameter	Value	Exposure time	Species	Environment
LC_{50}	20.5 mg/l	96 hours	Fish	Fresh water
EC_{50}	0.73 mg/l	72 hours	Algae	Fresh water
NOEC	0.36 mg/l	72 hours	Algae	Fresh water
EC_{50}	0.23 mg/l		Microorganisms	
EC_{50}	0.45 mg/l	48 hours	Crustaceans	

More information

The environmental effects of the product have not been thoroughly investigated. Data on toxicological effects of the hazardous ingredients are provided bellow.

12.2. Persistence and degradability

Hydrochloric acid:
The physicochemical properties indicate that the hydrogen chloride released into the environment is distributed both in air than in water. The hydrochloric acid is dissociated in the water into hydronium ion and chloride ion.

12.3. Bioaccumulative potential

Hydrochloric acid:
Considering the great water solubility of hydrogen chloride a significant bioconcentration in organisms is not expected.

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

Hydrochloric acid solution may cause adverse environmental effects due to decreasing pH. The pH of the receiving water depends on its buffer and on the amount of hydrochloric acid entered. In general, the mortality can be observed at pH values lower than 5.

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).

National regulations (Germany)

WGK Water hazard class:	nwg - non-hazardous to water

15.2. Chemical safety assessment

A chemical safety assessment has not been carried out for the mixture.

SECTION 16: Other information

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

H290	May be corrosive to metals.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
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.

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
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
Met. Corr.	Corrosive to metals
Skin Corr.	Skin corrosion
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 3.0 replaces the SDS version from 07 September 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.