

Trade name: Glucose/Lactate system solution and Glucose/Lactate hemolyzing solution

Current version : 9.1.1, issued: 12.05.2020

Replaced version: 9.1.0, issued: 12.05.2020

Region: GB

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

1.1 Product identifier

Trade name

**Glucose/Lactate system solution and Glucose/Lactate hemolyzing solution
System solution**

0201-0002-024

0201-0002-026

0201-0002-025

Micro test tubes with hemolyzing solution

0209-0100-012

0209-0100-013

0209-0100-014

0209-0100-050

0209-0100-005

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

Relevant identified uses of the substance or mixture

Glucose/Lactate hemolyzing solution:

Bottles and micro test tubes with hemolyzing solution with or without end-to-end capillaries are used to carry out 1 + 50 dilution [hemolysis] of blood for the determination of glucose and lactate. These 1 + 50 dilutions can be measured using the devices BIOSEN.

Glucose/Lactate system solution:

Glucose/Lactate system solution used in the devices BIOSEN to condition the biosensor and as a rinsing and transport solution. Glucose/Lactate system solution can also be used as a hemolyzing solution (sample dilution: 1 + 50) in the BIOSEN devices.

Uses advised against

No data available.

1.3 Details of the supplier of the safety data sheet

Address

EKF-diagnostic GmbH
Ebendorfer Chaussee 3
39179 Barleben
Germany

Telephone no. +49(0)39203511-0

Fax no. +49(0)39203511-171

Information provided by / telephone

Telephone number +49(0)39203511-0

Advice on Safety Data Sheet

support@ekf-diagnostic.de

1.4 Emergency telephone number

For medical advice (in German and English):

+49 (0)551 192 40 (Giftinformationszentrum Nord)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

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Classification information

This product is assessed and classified using the methods and criteria below referred to in Article 9 of Regulation (EC) n° 1272/2008:

Physical hazards: determined through assessment data based on the methods or standards referred to in part 2 of Annex I to CLP

Health hazards and environmental hazards: determined through toxicological and ecotoxicological assessment data based on the methods or standards referred to in Part 3, 4 and 5 of Annex I to CLP.

This product does not meet the classification criteria given in the Regulation (EC) No 1272/2008 (CLP).

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008 (CLP Regulation)

Hazard pictograms

-

Signal word

-

Hazard statement(s)

-

Hazard statements (EU)

EUH208

Contains reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H -isothiazol-3-one [EC no. 220-239-6] (3:1), 2-methyl-2H-isothiazol-3-one. May produce an allergic reaction.

EUH210

Safety data sheet available on request.

Precautionary statement(s)

-

Labelling information

The labelling (EU hazard statements) meets the criteria of annex II of Directive (EC) Nr. 1272/2008 (CLP).

2.3 Other hazards

No special hazards have to be mentioned. Please observe the information given in this safety data sheet.

SECTION 3: Composition/information on ingredients

3.1 Substances

Not applicable. The product is not a substance.

3.2 Mixtures

Chemical characterization

aqueous solution

Hazardous ingredients

No	Substance name		Additional information	
	CAS / EC / Index / REACH no	Classification (EC) 1272/2008 (CLP)	Concentration	%
1	reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H -isothiazol-3-one [EC no. 220-239-6] (3:1)			
	55965-84-9 - 613-167-00-5 -	Acute Tox. 2; H310 Acute Tox. 2; H330 Acute Tox. 3; H301 Aquatic Acute 1; H400 Aquatic Chronic 1; H410 EUH071 Eye Dam. 1; H318 Skin Corr. 1C; H314 Skin Sens. 1A; H317	< 0.0015	%-b.w.
2	2-methyl-2H-isothiazol-3-one			
	2682-20-4	Acute Tox. 2; H330	< 0.10	%-b.w.

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220-239-6 613-326-00-9 -	Acute Tox. 3; H301 Acute Tox. 3; H311 Aquatic Acute 1; H400 Aquatic Chronic 1; H410 EUH071 Eye Dam. 1; H318 Skin Corr. 1B; H314 Skin Sens. 1A; H317		
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Full Text for all H-phrases and EUH-phrases: pls. see section 16

No	Note	Specific concentration limits	M-factor (acute)	M-factor (chronic)
1	B	Skin Sens. 1A; H317: C \geq 0.0015% Eye Irrit. 2; H319: C \geq 0.06% Skin Irrit. 2; H315: C \geq 0.06% Skin Corr. 1C; H314: C \geq 0.6% Eye Dam. 1; H318: C \geq 0.6%	M = 100	M = 100
2	-	Skin Sens. 1A; H317: C \geq 0.0015%	M = 10	M = 1

Full text for the notes: pls. see section 16 "Notes relating to the identification, classification and labelling of substances ((EC) No 1272/2008, Annex VI)".

SECTION 4: First aid measures

4.1 Description of first aid measures

General information

In case of persisting adverse effects, consult a physician. Remove contaminated clothing and shoes immediately, and launder thoroughly before reusing.

After inhalation

Remove affected person from the immediate area. Ensure supply of fresh air.

After skin contact

Wash off immediately with soap and water.

After eye contact

Separate eyelids, wash the eyes thoroughly with water (15 min.).

After ingestion

Never give anything by mouth to an unconscious person. If individual is drowsy or unconscious, place in recovery position (on left side, with head down). Rinse out mouth and give plenty of water to drink.

4.2 Most important symptoms and effects, both acute and delayed

No data available.

4.3 Indication of any immediate medical attention and special treatment needed

No data available.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media

Product itself is non-combustible; adapt fire extinguishing measures to surrounding areas.

Unsuitable extinguishing media

No data available.

5.2 Special hazards arising from the substance or mixture

None known.

5.3 Advice for firefighters

Use self-contained breathing apparatus. Wear protective clothing.

SECTION 6: Accidental release measures

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6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Refer to protective measures listed in sections 7 and 8. Ensure adequate ventilation.

For emergency responders

No data available. Personal protective equipment (PPE) - see Section 8.

6.2 Environmental precautions

Do not discharge into the drains/surface waters/groundwater.

6.3 Methods and material for containment and cleaning up

Pick up with absorbent material (e.g., sand, sawdust, general-purpose binder). Send in suitable containers for recovery or disposal.

6.4 Reference to other sections

No data available.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Advice on safe handling

Ensure adequate ventilation.

General protective and hygiene measures

Do not eat, drink or smoke during work time. Keep away from foodstuffs and beverages. Avoid contact with eyes and skin. Remove soiled or soaked clothing immediately. Wash hands before breaks and after work.

Advice on protection against fire and explosion

No special measures necessary.

7.2 Conditions for safe storage, including any incompatibilities

Technical measures and storage conditions

Keep container tightly closed in a cool, well-ventilated place.

Recommended storage temperature

Value 15 - 25 °C

Requirements for storage rooms and vessels

Containers which are opened must be carefully closed and kept upright to prevent leakage. Always keep in containers of same material as the original.

Incompatible products

Store the foodstuffs separately.

7.3 Specific end use(s)

No data available.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

No parameters available for monitoring.

8.2 Exposure controls

Appropriate engineering controls

No data available.

Personal protective equipment

Respiratory protection

No special measures required.

Eye / face protection

Safety glasses (EN 166)

Hand protection

Protective gloves (recommended)

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Other

Standard laboratory clothing.

Environmental exposure controls

No data available.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Form/Colour	
liquid	
colourless	
Odour	
odourless	
Odour threshold	
No data available	
pH value	
Value	7.24
Reference temperature	20 °C
Boiling point / boiling range	
Value	appr. 100 °C
Reference pressure	1013 mbar
Melting point / melting range	
No data available	
Decomposition point / decomposition range	
No data available	
Flash point	
No data available	
Auto-ignition temperature	
No data available	
Oxidising properties	
No data available	
Explosive properties	
No data available	
Flammability (solid, gas)	
No data available	
Lower flammability or explosive limits	
No data available	
Upper flammability or explosive limits	
No data available	
Vapour pressure	
No data available	
Vapour density	
No data available	
Evaporation rate	
No data available	
Relative density	
No data available	

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Density	
No data available	
Solubility in water	
Comments	soluble
Solubility(ies)	
No data available	
Partition coefficient: n-octanol/water	
No data available	
Viscosity	
No data available	

9.2 Other information

Other information
No data available.

SECTION 10: Stability and reactivity

10.1 Reactivity

Dangerous reactions are not expected if the product is handled according to its intended use.

10.2 Chemical stability

Stable under recommended storage and handling conditions (See section 7).

10.3 Possibility of hazardous reactions

None, when used as directed.

10.4 Conditions to avoid

None known

10.5 Incompatible materials

none, if handled according to order

10.6 Hazardous decomposition products

No hazardous decomposition products if stored and handled as prescribed.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute oral toxicity
No data available
Acute dermal toxicity
No data available
Acute inhalational toxicity
No data available
Skin corrosion/irritation
No data available
Serious eye damage/irritation
No data available
Respiratory or skin sensitisation
No data available
Germ cell mutagenicity
No data available
Reproduction toxicity
No data available

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Carcinogenicity
No data available
STOT - single exposure
No data available
STOT - repeated exposure
No data available
Aspiration hazard
No data available
Delayed and immediate effects as well as chronic effects from short and long-term exposure
When handled appropriately adverse health effects are not to be expected.
Other information
The product was classified in toxicological terms on the basis of the results of the calculation procedure outlined within General Directive on Preparations (1999/45/EC).

SECTION 12: Ecological information

12.1 Toxicity

Toxicity to fish (acute)
No data available
Toxicity to fish (chronic)
No data available
Toxicity to Daphnia (acute)
No data available
Toxicity to Daphnia (chronic)
No data available
Toxicity to algae (acute)
No data available
Toxicity to algae (chronic)
No data available
Bacteria toxicity
No data available

12.2 Persistence and degradability

No data available.

12.3 Bioaccumulative potential

No data available.

12.4 Mobility in soil

No data available.

12.5 Results of PBT and vPvB assessment

No data available.

12.6 Other adverse effects

No data available.

12.7 Other information

Other information
Do not discharge into the drains or waters and do not store on public depositories.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

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Product

Allocation of a waste code number, according to the European Waste Catalogue, should be carried out in agreement with the regional waste disposal company.

Packaging

Contaminated packaging should be emptied as far as possible and after appropriate cleansing may be taken for reuse. Packaging that cannot be cleaned should be disposed of in agreement with the regional waste disposal company.

SECTION 14: Transport information

14.1 Transport ADR/RID/ADN

The product is not subject to ADR/RID/ADN regulations.

14.2 Transport IMDG

The product is not subject to IMDG regulations.

14.3 Transport ICAO-TI / IATA

The product is not subject to ICAO-TI / IATA regulations.

14.4 Other information

No data available.

14.5 Environmental hazards

Information on environmental hazards, if relevant, please see 14.1 - 14.3.

14.6 Special precautions for user

No data available.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Not relevant

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

EU regulations

Regulation (EC) No 1907/2006 (REACH) Annex XIV (List of substances subject to authorisation)

According to the data available and/or specifications supplied by upstream suppliers, this product does not contain any substances considered as substances requiring authorisation as listed on Annex XIV of the REACH regulation (EC) 1907/2006.

REACH candidate list of substances of very high concern (SVHC) for authorisation

According to available data and the information provided by preliminary suppliers, the product does not contain substances that are considered substances meeting the criteria for inclusion in annex XIV (List of Substances Subject to Authorisation) as laid down in Article 57 and article 59 of REACH (EC) 1907/2006.

Regulation (EC) No 1907/2006 (REACH) Annex XVII: RESTRICTIONS ON THE MANUFACTURE, PLACING ON THE MARKET AND USE OF CERTAIN DANGEROUS SUBSTANCES, PREPARATIONS AND ARTICLES

According to the data available and/or specifications supplied by upstream suppliers, this product does not contain any substances requiring authorisation as listed on Annex XVII of the REACH regulation (EC) 1907/2006.

Directive 2012/18/EU on the control of major-accident hazards involving dangerous substances

This product is not subject to Part 1 or 2 of Annex I.

15.2 Chemical safety assessment

No data available.

SECTION 16: Other information

Sources of key data used to compile the data sheet:

Regulation (EC) No 1907/2006 (REACH), 1272/2008 (CLP) as amended in each case.

EC Directives 2000/39/EC, 2006/15/EC, 2009/161/EU

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National Threshold Limit Values of the corresponding countries as amended in each case.
Transport regulations according to ADR, RID, IMDG, IATA as amended in each case.
The data sources used to determine physical, toxic and ecotoxic data, are indicated directly in the corresponding chapter.

Full text of the H- and EUH- phrases drawn up in sections 2 and 3 (provided not already drawn up in these sections)

EUH071	Corrosive to the respiratory tract.
H301	Toxic if swallowed.
H310	Fatal in contact with skin.
H311	Toxic in contact with skin.
H314	Causes severe skin burns and eye damage.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H330	Fatal if inhaled.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.

Notes relating to the identification, classification and labelling of substances and mixtures ((EC) No 1272/2008, Annex VI)

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.
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Department issuing safety data sheet

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This information is based on our present knowledge and experience.
The safety data sheet describes products with a view to safety requirements.
It does not however, constitute a guarantee for any specific product properties and shall not establish a legally valid contractual relationship.

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