

Trade name: Glucose/Lactate/Multi-Standard, Linearity test glucose/lactate and sensor test solution

Current version: 9.1.2, issued: 28.10.2022 Replaced version: 9.1.1, 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/Multi-Standard, Linearity test glucose/lactate and sensor test solution

Standard solutions for glucose/lactate analyzers

5211-3015

5211-3017

Test solutions

0209-0102-391

5130-6055

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

Relevant identified uses of the substance or mixture

The standard is used for calibration with the devices BIOSEN.

Linearity solution is used to verify the precision of the devices BIOSEN.

Sensor test solution is used to check the selectivity of chip sensor glucose or lactate with the devices BIOSEN.

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

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



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

Hazard pictograms

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Signal word

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Hazard statement(s)

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Hazard statements (EU)

EUH208 Contains reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-2H -

isothiazol-3-one (3:1), 2-methyl-2H-isothiazol-3-one. May produce an allergic reaction.

EUH210 Safety data sheet available on request.

Precautionary statement(s)

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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		Add	ditional information	
	CAS / EC / Index /	Classification (EC) 1272/2008 (CLP)	Cor	ncentration	%
	REACH no				
1	reaction mass of: 5	i-chloro-2-methyl-4-isothiazolin-3-one and 2-			
	methyl-2H -isothiaz	zol-3-one (3:1)			
	55965-84-9	Acute Tox. 2; H310	<	0.0015	wt%
	-	Acute Tox. 2; H330			
	613-167-00-5	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			
2	2-methyl-2H-isothia	azol-3-one			
	2682-20-4	Acute Tox. 2; H330	<	0.10	wt%
	220-239-6	Acute Tox. 3; H301			
	613-326-00-9	Acute Tox. 3; H311			
	-	Aquatic Acute 1; H400			
		Aquatic Chronic 1; H410			
		EÚH071			
		Eye Dam. 1; H318			
		Skin Corr. 1B; H314			
		Skin Sens. 1A; H317			

Full Text for all H-phrases and EUH-phrases: pls. see section 16

No	Note	Specific concentration limits	M-factor	M-factor
			(acute)	(chronic)



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1	В	Skin Sens. 1A; H317: C >= 0.0015%	M = 100	M = 100
		Eye Irrit. 2; H319: C >= 0.06%		
		Skin Irrit. 2; H315: C >= 0.06%		
		Skin Corr. 1C; H314: C >= 0.6%		
		Eye Dam. 1; H318: C >= 0.6%		
2	-	Skin Sens. 1A; H317: C >= 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 eve 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

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.

DIAGNOSTIC

Safety data sheet in accordance with 1907/2006/EC

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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 2 - 8 °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)

Other

Standard laboratory clothing.

Environmental exposure controls

No data available.

State of aggregation

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

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liquid
Farms



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liquid				
Colour colourless				
Odour odourless				
pH value Value Reference temperature		7.24 20	°C	
Boiling point / boiling range Value Reference pressure	appr.	100 1013	°C mbar	
Melting point/freezing point No data available				
Decomposition temperature No data available				
Flash point No data available				
Ignition temperature No data available				
Flammability No data available				
Lower explosion limit No data available				
Upper explosion limit No data available				
Vapour pressure No data available				
Relative vapour density No data available				
Relative density No data available				
Density No data available				
Solubility in water Comments	soluble			
Solubility No data available				
Partition coefficient n-octanol/water (log v No data available	alue)			
Kinematic viscosity No data available				
Particle characteristics No data available				
2 Other information Other information				

No data available.

DIAGNOSTIC

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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 hazard classes as defined in Regulation (EC) No 1272/2008

Acute oral toxicity

Acute dermal toxicity

No data available

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

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.

11.2 Information on other hazards

Endocrine disrupting properties

No data available.

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Other information

No data available.

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 Endocrine disrupting properties

No data available.

12.7 Other adverse effects

No data available.

12.8 Other information

Other information

Do not discharge into drains or waters and do not dispose of in public landfills.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

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.



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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 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 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, MIXTURES AND ARTICLES

The product contains following substance(s) that are considered being subject to REACH regulation (EC) 1907/2006 annex XVII.

No	Substance name	CAS no.	EC no.	No
1	reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-	55965-84-9	-	75
	one and 2-methyl-2H -isothiazol-3-one (3:1)			

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.

Directives 2000/39/EC, 2006/15/EC, 2009/161/EU, (EU) 2017/164.

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 section.

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.



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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)

В

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

Creation of the safety data sheet

UMCO GmbH

Georg-Wilhelm-Str. 187, D-21107 Hamburg

Tel.: +49 40 / 555 546 300 Fax: +49 40 / 555 546 357 e-mail: umco@umco.de

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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