

Trade name: Glucose control solution, Level II for LABTREND

Last revised: 01.12.2016

Replaced version: 2.2

effective date: 21.12.2023

version: 3.0

1. Identification of the substance or mixture and of the company

1.1 Product identifier:

Product Name: Glucose control solution, Level II

Product-Number: 37 000001, 37 000010

REACH Number: This product is a mixture. REACH registration numbers see section 3.

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

Relevant identified uses: Glucose control solution for LABTREND is intended to be used as a control sample.

Uses advised against: Do not use for products which come into contact with foodstuffs. Do not use for private purposes (household).

1.3 Details of the supplier of the safety data sheet

Manufacturer / Supplier: BST Bio Sensor Technology GmbH
Buchholzer Str. 58
D - 13156 Berlin
Germany

E-Mail (competent person): support@bst-biosensor.de

Phone: 0049 30 7676731-0

Fax: 0049 30 7676731-28

1.4 Emergency telephone number

Emergency Information Service: 0049 89 19240
(Poison Center Munich, Ismaninger Str. 22, 81675 Munich)

2. Composition / Information on Hazardous Ingredients

2.1 Classification of the substance or mixture

Regulation (EC) No. 1272/2008

Skin Sens. / H317 May cause an allergic skin reaction.

Trade name: Glucose control solution, Level II for *LABTREND*

Last revised: 01.12.2016

Replaced version: 2.2

effective date: 21.12.2023

version: 3.0

2.2 Label elements

The product is classified and labeled according to EC guidelines or the respective national laws.

Labeling according to Regulation (EC) No. 1272/2008 (CLP)

Hazard pictograms



Signal word: **Warning (GHS07)**

Hazard statement(s)

H317 May cause an allergic skin reaction.

Precautionary statement(s)

P261 Avoid breathing dust/mist or vapours.
P272 Contaminated work clothing should not be allowed out of the workplace.
P280 Wear protective gloves/protective clothing/eye protection/face protection
P302 + P352 IF ON SKIN: wash with plenty of water.
P333 + P317 If skin irritation or rash occurs: Get medical help.
P362 + P364 Take off contaminated clothing and wash it before reuse.

Hazard-determining components for labeling

Hazardous Ingredients: mixture of 5-CHLOR-2-METHYL-2H-ISOTHIAZOL-3ON and 2-METHYL-2H-ISOTHIAZOL-3ON (3:1) [EG Nr. 55965-84-9]
Concentration > 0.0015 %

Additional hazard characteristics

EUH208 Contains reaction mass of 5-Chloro-2-methyl-2H-isothiazol-3-one and 2-Methyl-2H-isothiazol-3-one (3:1). May produce an allergic reaction.

2.3 Other hazards

This mixture does not contain any components at concentrations $\geq 0.1\%$ that are classified as either persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB).

Trade name: Glucose control solution, Level II for *LABTREND*

Last revised: 01.12.2016

Replaced version: 2.2

effective date: 21.12.2023

version: 3.0

3. Hazards Identification

3.2 Mixtures

Hazardous Ingredients

Name of substance	Identifier	Wt%	Classification acc. to GHS
reaction mass of 5-Chloro-2-methyl-2H-isothiazol-3-one and 2-Methyl-2H-isothiazol-3-one (3:1)	CAS-No. 55965-84-9 EC-No. 911-418-6 Index-No. 613-167-00-5	0,0075	Skin Sens. 1A / H317 (C ≥ 0,0015 %)

(For further information see section 11.1)

4. First-Aid Measures

4.1 Description of first aid measures



General notes

Take off contaminated clothing.

Following inhalation

Provide fresh air. In all cases of doubt, or when symptoms persist, seek medical advice.

Following skin contact

Rinse skin with water/shower. In all cases of doubt, or when symptoms persist, seek medical advice.

Following eye contact

Rinse cautiously with water for several minutes. In all cases of doubt, or when symptoms persist, seek medical advice.

Following ingestion

Rinse mouth. Call a doctor if you feel unwell.

4.2 Most important symptoms and effects, both acute and delayed

Allergic reactions

4.3 Indication of any immediate medical attention and special treatment needed

none

Trade name: Glucose control solution, Level II for *LABTREND*

Last revised: 01.12.2016

Replaced version: 2.2

effective date: 21.12.2023

version: 3.0

5. Firefighting measures

5.1 Extinguishing media



Suitable extinguishing media

coordinate firefighting measures to the fire surroundings
water spray, alcohol resistant foam, dry extinguishing powder, BC-powder, carbon dioxide (CO₂)

Unsuitable extinguishing media

water jet

5.2 Special hazards arising from the substance or mixture

Non-combustible.

5.3 Advice for firefighters

In case of fire and/or explosion do not breathe fumes. Fight fire with normal precautions from a reasonable distance. Wear self-contained breathing apparatus.

6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures



Ventilate area, see precautionary statements in section 2.2.

6.2 Environmental precautions

Keep away from drains, surface and ground water.

6.3 Methods and material for containment and cleaning up

Contain spillage, and then collect with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local / national regulations (see section 13).

Trade name: Glucose control solution, Level II for LABTREND

Last revised: 01.12.2016

Replaced version: 2.2

effective date: 21.12.2023

version: 3.0

6.4 Reference to other sections

Observe protective regulations (see sections 7 and 8).

7. Handling and Storage

7.1 Precautions for safe handling

(see section 2.2)

Advice on general occupational hygiene

Keep away from food, drink and animal feedingstuffs.

7.2 Conditions for safe storage, including any incompatibilities

Storage conditions: Keep container tightly closed.

Recommended storage temp.: see product label

Storage class: Storage class (TRGS 510): 12: Non-flammable liquids

7.3 Specific end use(s)

Apart from the use stated in section 1.2, no other specific uses are intended.

8. Exposure controls and personal protection

8.1 Control parameters

National limit values

Occupational exposure limit values (Workplace Exposure Limits)

This information is not available (TRGS 900).

Relevant DNELs of components of the mixture

Name of substance	Identifier	Endpoint	Threshold level	Protection goal, route of exposure	Used in	Exposure time
reaction mass of 5-Chloro-2-methyl-2H-isothiazol-3-one and 2-Methyl-2H-isothiazol-3-one (3:1)	CAS-No. 55965-84-9 EC-No. 911-418-6 Index-No. 613-167-00-5	DNEL	0,02 mg/m ³	human, inhalatory	worker (industry)	chronic - local effects
reaction mass of 5-Chloro-2-methyl-2H-isothiazol-3-one and 2-Methyl-2H-isothiazol-3-one (3:1)	CAS-No. 55965-84-9 EC-No. 911-418-6 Index-No. 613-167-00-5	DNEL	0,04 mg/m ³	human, inhalatory	worker (industry)	acute - local effects

Trade name: Glucose control solution, Level II for LABTREND

Last revised: 01.12.2016

Replaced version: 2.2

effective date: 21.12.2023

version: 3.0

Relevant PNECs of components of the mixture

Name of substance	Identifier	Endpoint	Threshold level	Organism	Environmental compartment	Exposure time
reaction mass of 5-Chloro-2-methyl-2H-isothiazol-3-one and 2-Methyl-2H-isothiazol-3-one (3:1)	CAS-No. 55965-84-9 EC-No. 911-418-6 Index-No. 613-167-00-5	PNEC	3,39 µg/l	aquatic organisms	water	short-term (single instance)
reaction mass of 5-Chloro-2-methyl-2H-isothiazol-3-one and 2-Methyl-2H-isothiazol-3-one (3:1)	CAS-No. 55965-84-9 EC-No. 911-418-6 Index-No. 613-167-00-5	PNEC	0,027 mg/kg	aquatic organisms	sediment	short-term (single instance)
reaction mass of 5-Chloro-2-methyl-2H-isothiazol-3-one and 2-Methyl-2H-isothiazol-3-one (3:1)	CAS-No. 55965-84-9 EC-No. 911-418-6 Index-No. 613-167-00-5	PNEC	0,01 mg/kg	terrestrial organisms	soil	short-term (single instance)

8.2 Exposure controls

Individual protection measures (personal protective equipment)

Eye/face protection



Use safety goggle with side protection if necessary.

Skin protection



Trade name: Glucose control solution, Level II for LABTREND

Last revised: 01.12.2016

Replaced version: 2.2

effective date: 21.12.2023

version: 3.0

hand protection

Wear suitable gloves. Chemical protection gloves are suitable, which are tested according to EN 374 (type of material: NBR -Nitrile rubber; material thickness > 0,11 mm; breakthrough times of the glove material > 480 minutes – permeation: level 6)

Take recovery periods for skin regeneration. Preventive skin protection (barrier creams / ointments) is recommended.

Respiratory protection

Respiratory protection necessary at: Aerosol or mist formation. Usually no personal respirative protection necessary.

Environmental exposure controls

Keep away from drains, surface and ground water.

9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

a) Physical state	liquid
b) Colour	colourless
c) Odour	odourless
d) Melting point/freezing point	not determined
e) Boiling point or initial boiling point and boiling range	approx. 100°C (1013 mbar)
f) Flammability	non-combustible
g) Lower and upper explosion limit	not determined
h) Flash point	not determined
i) Auto-ignition temperature	not determined
j) Decomposition temperature	not relevant
k) pH-value	6,8 – 7,3
l) Kinematic viscosity	not determined
m) Water solubility	miscible in any proportion
n) Partition coefficient n-octanol/water (log value):	not relevant
o) Vapour pressure	23 hPa at 20 °C
p) Density	~ 1,03 g/cm ³ (20°C)
q) Relative vapour density	no information available
r) Particle characteristics	not relevant (liquid)
s) Explosive properties	not classified
t) Oxidising properties	none

Trade name: Glucose control solution, Level II for *LABTREND*

Last revised: 01.12.2016

Replaced version: 2.2

effective date: 21.12.2023

version: 3.0

10. Stability and Reactivity

10.1 Reactivity

This material is not reactive under normal ambient conditions.

10.2 Chemical stability

The material is stable under normal ambient and anticipated storage and handling conditions of temperature and pressure.

10.3 Possibility of hazardous reactions

No known hazardous reactions.

10.4 Conditions to avoid

Avoid contact with oxidizing or reducing agents.

10.5 Incompatible materials

There is no additional information.

10.6 Hazardous decomposition products

Hazardous combustion products: see section 5.

11. Toxicological Information

11.1 Information on toxicological effects

Test data are not available for the complete mixture.

Classification procedure

The method for classification of the mixture is based on ingredients of the mixture.

Classification acc. to GHS (1272/2008/EG, CLP, amended by Regulation (EU) 2023/1435)

Hazard class 3.4 - skin sensitisation

Acute toxicity

According to Regulation (EC) No. 1272/2008, mixture is not classified as acutely toxic.

Hazardous Ingredients

Name of substance	Identifier	Specific Conc. Limits	M-Factors	ATE	Exposure route
reaction mass of 5-Chlor-2-methyl-2H-isothiazol-3-on und 2-Methyl-2H-isothiazol-3-on (3:1)	CAS-No. 55965-84-9 EG-Nr. 911-418-6 Index-Nr. 613-167-00-5	Skin Corr. 1C: H314; C ≥ 0,6% Skin Irrit. 2; H315: 0,06 % ≤ C < 0,6% Eye Dam. 1; H318: C ≥ 0,6% Eye Irrit. 2; H319: 0,06 % ≤ C < 0,6% Skin Sens. 1A; H317: C ≥ 0,0015%	acute = 100 chronic = 100	100 mg/kg 50 mg/kg 0,5 mg/l/4h 0,05 mg/l/4h	oral dermal inhalation: vapour inhalation: dust/mist

Trade name: Glucose control solution, Level II for LABTREND

Last revised: 01.12.2016

Replaced version: 2.2

effective date: 21.12.2023

version: 3.0

Acute toxicity of components of the mixture

Name of substance	Identifier	Exposure route	Endpoint	Wert	Spezies
reaction mass of 5-Chloro-2-methyl-2H-isothiazol-3-one and 2-Methyl-2H-isothiazol-3-one (3:1)	CAS-No. 55965-84-9 EC-No. 911-418-6 Index-No. 613-167-00-5	oral	LD50	457 mg/kg	rat
reaction mass of 5-Chloro-2-methyl-2H-isothiazol-3-one and 2-Methyl-2H-isothiazol-3-one (3:1)	CAS-No. 55965-84-9 EC-No. 911-418-6 Index-No. 613-167-00-5	inhalation: dust/mist	LC50	2,36 mg//4h	rat
reaction mass of 5-Chloro-2-methyl-2H-isothiazol-3-one and 2-Methyl-2H-isothiazol-3-one (3:1)	CAS-No. 55965-84-9 EC-No. 911-418-6 Index-No. 613-167-00-5	dermal	LD50	660 mg/kg	rabbit

Skin corrosion/irritation

Shall not be classified as corrosive/irritant to skin.

Serious eye damage/eye irritation

Shall not be classified as seriously damaging to the eye or eye irritant.

Respiratory or skin sensitisation

Contains Reaction mass of 5-Chloro-2-methyl-2H-isothiazol-3-one and 2-Methyl-2H-isothiazol-3-one (3:1). May produce an allergic reaction.

Germ cell mutagenicity

Shall not be classified as germ cell mutagenic.

Carcinogenicity

Shall not be classified as carcinogenic.

Trade name: Glucose control solution, Level II for *LABTREND*

Last revised: 01.12.2016

Replaced version: 2.2

effective date: 21.12.2023

version: 3.0

Reproductive toxicity

Shall not be classified as a reproductive toxicant.

Specific target organ toxicity - single exposure

Shall not be classified as a specific target organ toxicant (single exposure).

Specific target organ toxicity - repeated exposure

Shall not be classified as a specific target organ toxicant (repeated exposure).

Aspiration hazard

Shall not be classified as presenting an aspiration hazard.

11.2 Additional Information

Endocrine disrupting properties

This mixture does not contain any ingredients that have endocrine disrupting properties at levels of 0.1% or more as defined in REACH Article 57(f) or Commission Delegated Regulation (EU) 2017/2100 or Commission Delegated Regulation (EU) 2018/605 .

12. Ecological Information

12.1 Toxicity

(Acute) aquatic toxicity of components of the mixture

Name of substance	Identifier	Endpoint	Value	Species	Exposure time
reaction mass of 5-Chloro-2-methyl-2H-isothiazol-3-one and 2-Methyl-2H-isothiazol-3-one (3:1)	CAS-No. 55965-84-9 EC-No. 911-418-6 Index-No. 613-167-00-5	LC50	0,19 mg/l	fish	96 h
reaction mass of 5-Chloro-2-methyl-2H-isothiazol-3-one and 2-Methyl-2H-isothiazol-3-one (3:1)	CAS-No. 55965-84-9 EC-No. 911-418-6 Index-No. 613-167-00-5	EC50	0,16 mg/l	aquatic invertebrates	48 h
reaction mass of 5-Chloro-2-methyl-2H-isothiazol-3-one and 2-Methyl-2H-isothiazol-3-one (3:1)	CAS-No. 55965-84-9 EC-No. 911-418-6 Index-No. 613-167-00-5	ErC50	19,9 µg/l	algae	72 h

Trade name: Glucose control solution, Level II for LABTREND

Last revised: 01.12.2016

Replaced version: 2.2

effective date: 21.12.2023

version: 3.0

(Chronic) aquatic toxicity of components of the mixture

Name of substance	Identifier	Endpoint	Value	Species	Exposure time
reaction mass of 5-Chloro-2-methyl-2H-isothiazol-3-one and 2-Methyl-2H-isothiazol-3-one (3:1)	CAS-No. 55965-84-9 EC-No. 911-418-6 Index-No. 613-167-00-5	LC50	0,07 mg/l	fish	14 d
reaction mass of 5-Chloro-2-methyl-2H-isothiazol-3-one and 2-Methyl-2H-isothiazol-3-one (3:1)	CAS-No. 55965-84-9 EC-No. 911-418-6 Index-No. 613-167-00-5	EC50	> 0,18 mg/l	aquatic invertebrates	21 d
reaction mass of 5-Chloro-2-methyl-2H-isothiazol-3-one and 2-Methyl-2H-isothiazol-3-one (3:1)	CAS-No. 55965-84-9 EC-No. 911-418-6 Index-No. 613-167-00-5	ErC50	45,6 µg/l	algae	120 h

12.2 Persistence and degradability

Degradability of components of the mixture

Name of substance	Identifier	Process	Degradation rate	Time	Source
reaction mass of 5-Chloro-2-methyl-2H-isothiazol-3-one and 2-Methyl-2H-isothiazol-3-one (3:1)	CAS-No. 55965-84-9 EC-No. 911-418-6 Index-No. 613-167-00-5	carbon dioxide generation	38,80%	29 d	ECHA

12.3 Bioaccumulative potential

Data are not available.

12.4 Mobility in soil

Data are not available.

12.5 Results of PBT and vPvB assessment

Data are not available.

12.6 Endocrine disrupting properties

None of the ingredients are listed.

Trade name: Glucose control solution, Level II for *LABTREND*

Last revised: 01.12.2016

Replaced version: 2.2

effective date: 21.12.2023

version: 3.0

12.7 Other adverse effects

Data are not available.

13. Disposal Considerations

13.1 Waste treatment methods

Product residues must be disposed of in compliance with national and regional regulations. Leave chemicals in original containers. Do not mix with other waste. Used containers must be treated appropriately for the product. Observe Waste Directive 2008/98/EC or Directive (EU) 2018/851.

14. Transportation Information

14.1 UN number or ID number is not subject to transport regulations

14.2 UN proper shipping name not assigned

14.3 Transport hazard classes none

14.4 Packaging group not assigned

14.5 Environmental hazards

non-environmentally hazardous acc. to the dangerous goods regulations

14.6 Special precautions for user

No additional information is available.

14.7 Maritime transport in bulk according to IMO instruments

The cargo is not intended to be carried in bulk.

14.8 Information according to the individual UN model regulations

Transport of dangerous goods by road, rail or inland waterways (ADR/RID/ADN) –

Additional information: Not subject to the regulations of ADR, RID and ADN.

International Code for the Carriage of Dangerous Goods by Sea Vessel (IMDG) –

Additional information: Not subject to the regulations of the IMDG.

International Civil Aviation Organization (ICAO-IATA/DGR) –

Additional information: Not subject to ICAO-IATA regulations.

Trade name: Glucose control solution, Level II for LABTREND

Last revised: 01.12.2016

Replaced version: 2.2

effective date: 21.12.2023

version: 3.0

15. Regulatory Information

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

This safety data sheet meets the requirements of Regulation (EU) 2017/746 for hazardous substances within the meaning of Article 5 (2) and Annex I, derived from Table 3 (Annex VI) of the CLP Regulation 1272/2008/EC, the REACH candidate list the SVHCs, the Directive 2000/54/EC Annex III (Biological Agents list) and the EU Framework Directive 89/391/EEC for risks arising from chemical, physical and biological effects in the workplace.

Further regulations

Regulation (EC) No. 1005/2009 for substances that deplete the ozone layer:

not listed

Regulation (EC) No. 850/2004 for persistent organic pollutants:

not listed

Regulation (EC) No. 649/2012 for the export and import of dangerous chemicals:

not listed

Directive 2011/65/EU on the restriction of the use of certain dangerous substances in electrical and electronic equipment:

not listed

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on Controlling the dangers of serious accidents involving dangerous substances:

not applicable

Other Information

Observe Directive 94/33/EC on youth labor protection and employment restrictions in accordance with Maternity Directive 92/85/EEC.

15.2 Chemical safety assessment

Chemical safety assessments for substances in this mixture have not been carried out.

Trade name: Glucose control solution, Level II for LABTREND

Last revised: 01.12.2016

Replaced version: 2.2

effective date: 21.12.2023

version: 3.0

16. Other Information

Abbreviation	Description of used abbreviations
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland shipping
ADR	Convention concerning the international carriage of dangerous goods by road
Aquatic Acute	Hazardous to the aquatic environment - acute hazard
Aquatic Chronic	Hazardous to the aquatic environment - chronic hazard
ATE	Acute Toxicity Estimate
CAS	Chemical Abstracts Service
CLP	Regulation (EC) No. 1272/2008 on classification, labeling and packaging of substances and mixtures
DNEL	Derived No-Effect Level
EC50	Effective Concentration 50%. The EC50 corresponds to the concentration of a tested substance that changes an effect (e.g. on growth) by 50% in a given period of time
EC-No.	The EC Inventory is the source for the seven-digit EC number as an identification number for substances in the EU
ECHA	European Chemicals Agency
ErC50	≡ EC50: in this method, the concentration of the test substance that leads to a 50% decrease in either growth (EbC50) or growth rate (ErC50) compared to the control
Eye Dam.	Seriously damaging to the eye
Eye Irrit.	Irritant to the eye
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
IATA/DGR	Dangerous Goods Regulations (DGR) for the air transport (IATA)
ICAO	International Civil Aviation Organisation
IMDG	International Maritime Dangerous Goods Code
index-No.	The index number is the identification code specified in Part 3 of Annex VI to Regulation (EC) No 1272/2008
LC50	Lethal Concentration 50%: the LC50 corresponds to the concentration of a tested substance causing 50 % lethality during a specified time interval
LD50	Lethal Dose 50%: the LD50 corresponds to the dose of a tested substance causing 50 % lethality during a specified time interval

Trade name: Glucose control solution, Level II for LABTREND

Last revised: 01.12.2016

Replaced version: 2.2

effective date: 21.12.2023

version: 3.0

M-Faktor	Multiplication factor, is applied to the concentration of a substance classified as acutely hazardous to the aquatic environment, category 1, or as chronically hazardous to the aquatic environment, category 1, and is used to enable the classification of a mixture in which the substance is present to be carried out using the summation method
PBT	Persistent, bioaccumulative and toxic
PNEC	Predicted No-Effect Concentration
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RID	Regulation for the international carriage of dangerous goods by rail
Skin Corr.	Corrosive to skin
Skin Irrit.	Irritant to skin
Skin Sens.	Skin sensitisation
SVHC	Substance of Very High Concern
TRGS	Technical rules for hazardous substances (Germany)
vPvB	Very persistent and very bioaccumulative

Important literature and data sources

Regulation (EC) No. 1272/2008 on the classification, labeling and packaging of substances and mixtures. Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU.

Disclaimer

Our products are examined for laboratory use only. The precautionary measures usual with chemicals are to be considered. The information data and recommendations contained herein are based upon information believed by BST GmbH, after reasonable investigation and research, to be accurate. BST GmbH does not warrant the accuracy of this information.