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

1.1 Product identifier
Trade Name: TopKon HbA1c Level 2
Article n°: 6110XXX
MS: 80115310151

1.2 Relevant identified uses of the substance or mixture and uses advised against
General use: Reagent for in-vitro diagnostics in human samples
For professional use only.

1.3 Details of the supplier of the safety data sheet
Kovalent do Brasil Ltda.
Rua Cristóvão Sardinha, 110 – Jd. Bom Retiro – São Gonçalo – RJ – Brasil.
Tel: +(55 21) 2623-1367
e-mail: kovalent@kovalent.com.br

1.4 Emergency telephone number
Tel: +(55 21) 2623-1367 – Costumer service 8AM to 5PM.
0800 015 1414

In case of emergency
24 hours service
0800-722-6001 – RENACIAT (Rede Nacional de Centros de Informação e Assistência Toxicológica)

2 Hazards Identification

2.1 Classification of the substance or mixture
Classification according to ABNT NBR 14725.
This mixture is classified as not hazardous.

2.2 Label elements

Labelling (GHS)

Hazard statements: Not applicable

Precautionary statements: Not applicable

Special labelling

EUH208: Contains Mixture of 5-chlorine-2-methyl-2H-isothiazol-3-on and 2-methylen-2H-isothiazol-3-on (3:1). May produce an allergic reaction.

EUH210: Safety data sheet available on request.

2.3 Other hazards
No risks worthy of mention.

Endocrine disrupting properties, Results of PBT and vPvB assessment:
No data available

3 Composition/information on ingredients

3.1 Substances
Not applicable

3.2 Mixtures
Chemical characterization: Aqueous solution

Hazardous ingredients:

Identifiers	Designation Classification	Content

List no. 611-341-5 CAS 55965-84-9	Mixture of 5-chlorine-2-methyl-2H-isothiazol-3-on and 2-methylen-2H-isothiazol-3-on (3:1) Acute Tox. 3; H301. Acute Tox. 2; H310. Acute Tox. 2; H330. Skin Corr. 1C; H314. Eye Dam. 1; H318. Skin Sens. 1A; H317. Aquatic Acute 1; H400. Aquatic Chronic 1; H410. (EUH071). Specific concentration limits (SCL): 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 % M-factors: Aquatic Acute 1: M = 100. Aquatic Chronic 1: M = 100.	< 0.0015 %

Full text of H- and EUH-statements: see section 16.

Additional information: Contains Sodium azide (0,18 g/L) as preservative.
Contains Glycerol: The maximum workplace exposure limits are, where necessary, listed in section 8.

4 First aid measures

4.1 Description of first aid measures

In case of inhalation: Move victim to fresh air. In case of respiratory difficulties seek medical attention.

Following skin contact: Take off contaminated clothing and wash it before reuse. After contact with skin, wash immediately with soap and plenty of water. In case of skin reactions, consult a physician.

After eye contact: Immediately flush eyes with plenty of flowing water for 10 to 15 minutes holding eyelids apart. Remove contact lenses, if present and easy to do. Continue rinsing. In case of troubles or persistent symptoms, consult an ophthalmologist.

After swallowing: Rinse mouth thoroughly with water. Do not induce vomiting without medical advice. Have victim drink large quantities of water, with active charcoal if possible. Never give anything by mouth to an unconscious person. Seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

May cause allergic reactions in already sensitized persons.

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

5 Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media: Product is non-combustible. Extinguishing materials should therefore be selected according to surroundings.

5.2 Special hazards arising from the substance or mixture

In the event of a fire, the following may be produced when the water evaporates: Carbon monoxide and carbon dioxide.

5.3 Advice for firefighters

Special protective equipment for firefighters: Wear self-contained breathing apparatus.

Additional information: Do not allow fire water to penetrate into surface or ground water.

6 Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Wear appropriate protective equipment. Provide adequate ventilation. Do not breathe vapours.
Avoid contact with skin and eyes. Take off contaminated clothing and wash it before reuse.

6.2 Environmental precautions

Do not allow to penetrate into soil, waterbodies or drains.

6.3 Methods and material for containment and cleaning up
Soak up with absorbent materials such as sand, siliceus earth, acid- or universal binder. Store in special closed containers and dispose of according to ordinance. Final cleaning.

6.4 Reference to other sections
Refer additionally to section 8 and 13.

7 Handling and storage

7.1 Precautions for safe handling

Advices on safe handling: Provide adequate ventilation, and local exhaust as needed. Avoid contact with skin, eyes, and clothing. Do not breathe vapours. After worktime and during work intervals the affected skin areas must be thoroughly cleaned. Take off contaminated clothing and wash it before reuse. Have eye wash bottle or eye rinse ready at work place.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storerooms and containers: Keep containers tightly closed and at a temperature between 2 °C and 8 °C. Do not freeze. Protect from light. Keep sterile.

Hints on joint storage: Do not store together with strong acids and alkalis. Keep away from food, drink and animal feedingstuffs.

Storage class: 12 = Non-combustible liquids

7.3 Specific end use(s)
No information available.

8 Exposure controls/personal protection

8.1 Control parameters

Occupational exposure limit values:

CAS No.	Designation	Type	Limit value
56-81-5	Glycerol	Germany: TRGS 900 Kurzzeit	400 mg/m³ (inhalable fraction)
		Germany: TRGS 900 Langzeit	200 mg/m³ (inhalable fraction)

8.2 Exposure controls
Provide good ventilation and/or an exhaust system in the work area.

Personal protection equipment
Occupational exposure controls

Respiratory protection: Respiratory protection must be worn whenever the WEL levels have been exceeded. Use combination filter type A/P according to EN 14387.

Hand protection: Protective gloves according to EN 374.
Glove material: Natural latex or Nitrile rubber 0,5 mm.
Breakthrough time: >480 min.
Observe glove manufacturer's instructions concerning penetrability and breakthrough time.

Eye protection: Tightly sealed goggles according to EN 166.

Body protection: Wear suitable protective clothing.

General protection and hygiene measures:
Do not breathe vapours. Take off contaminated clothing and wash it before reuse. Wash hands before breaks and after work. Do not eat, drink or smoke when using this product. Have eye wash bottle or eye rinse ready at work place.

Environmental exposure controls
Refer to "6.2 Environmental precautions".

9 Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state at 20 °C and 101.3 kPa	Liquid
Colour:	Red
Odour:	No characteristic odour
Odour threshold:	No data available
Melting point/freezing point:	No data available
Initial boiling point and boiling range:	No data available
Flammability:	No data available
Upper/lower flammability or explosive limits:	No data available
Flash point/flash point range:	Not combustible
Decomposition temperature:	No data available
pH:	Neutral
Viscosity, kinematic:	No data available
Water solubility:	No data available
Partition coefficient: n-octanol/water:	No data available
Vapour pressure:	No data available
Density:	at 20°C: 1.0084 g/mL
Vapour density:	No data available
Particle characteristics:	Not applicable

9.2 Other information

Explosive properties:	No data available
Oxidizing characteristics:	No data available
Auto-ignition temperature:	No data available
Evaporation rate:	No data available
Additional information:	No data available

10 Stability and reactivity

10.1 Reactivity
Refer to 10.3.

10.2 Chemical stability
Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions
No hazardous reactions known.

10.4 Conditions to avoid
Protect against heat /sun rays.

10.5 Incompatible materials
Strong acids and alkalis.

10.6 Hazardous decomposition products
No hazardous decomposition products when regulations for storage and handling are observed.

Thermal decomposition:	No data available

11 Toxicological information

Toxicological effects:	The statements are derived from the properties of the single components. No toxicological data is available for the product as such.
Acute toxicity (oral):	Lack of data.
Acute toxicity (dermal):	Lack of data.
Acute toxicity (inhalative):	Lack of data.
Skin corrosion/irritation:	Lack of data.
Serious eye damage/irritation:	Lack of data.
Sensitisation to the respiratory tract:	Lack of data.
Skin sensitisation:	Based on available data, the classification criteria are not met. Contains Mixture of 5-chlorine-2-methyl-2H-isothiazol-3-on and 2-methylen-2H-isothiazol-3-on (3:1). May produce an allergic reaction.
Germ cell mutagenicity/Genotoxicity:	Lack of data.
Carcinogenicity:	Lack of data.
Reproductive toxicity:	Lack of data.
Effects on or via lactation:	Lack of data.
Specific target organ toxicity: (single exposure)	Lack of data.
Specific target organ toxicity: (repeated exposure)	Lack of data.
Aspiration hazard:	Lack of data.
Endocrine disrupting properties:	No data available
Other information:	Contains Sodium azide (0,18 g/L): After resorption of toxic quantities: headache, dizziness, nausea, cough, vomiting, spasms, breathing paralysis, CNS disorders, low blood pressure, cardiovascular failure, unconsciousness, collapse.

12 Ecological information

12.1 Toxicity
Water Hazard Class: 1 = slightly hazardous to water

12.2 Persistence and degradability
Further details: No data available

12.3 Bioaccumulative potential
Partition coefficient: n-octanol/water: 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

General information: Do not allow to enter into ground-water, surface water or drains.

13 Disposal considerations

13.1 Waste treatment methods

Product: Dispose of waste according to applicable legislation.

Package: Dispose of waste according to applicable legislation.

Additional information: Do not reuse empty containers.

14 Transport information

14.1 UN number or ID number

ADR/RID, IMDG, IATA-DGR Not applicable

14.2 UN proper shipping name

ADR/RID, IMDG, IATA-DGR Not restricted

14.3 Transport hazard class(es)

ADR/RID, IMDG, IATA-DGR Not applicable

14.4 Risk Number

-

14.5 Packing group

ADR/RID, IMDG, IATA-DGR Not applicable

14.5 Environmental hazards

Dangerous for the environment: Substance/mixture is not environmentally hazardous according to the criteria of the UN model regulations.

Marine pollutant: No

14.6 Special precautions for user

No dangerous good in sense of these transport regulations.

15 Regulatory information

• Product produced in accordance with the requirements established by RDC 665 of 30/03/2022 and with labeling information in accordance with RDC 206 of 17/11/2006.

• For more details on product disposal refer to RDC 222 of 28/03/2018 and NBR 10004.

• This safety data sheet was prepared in accordance with ABNT/NBR 14725:23.

16 Other information

Wording of the H-phrases under paragraph 2 and 3:
H301 = Toxic if swallowed.
H310 = Fatal 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.
EUH071 = Corrosive to the respiratory tract.
EUH208 = Contains Mixture of 5-chlorine-2-methyl-2H-isothiazol-3-on and 2-methylen-2H-isothiazol-3-on (3:1). May produce an allergic reaction.
EUH210 = Safety data sheet available on request.

The above information is considered correct but is not intended to be complete and should be used only as a guide. Kovalent is not responsible for any damage resulting from handling or use.

In article XXX: The three X are for the volume.

Abbreviations and acronyms:
ABNT: Associação Brasileira de Normas Técnicas
Acute Tox.: Acute toxicity
ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road
Aquatic Acute: Hazardous to the aquatic environment - acute
Aquatic Chronic: Hazardous to the aquatic environment - chronic
AS/NZS: Australian Standards/New Zealand Standards
CAS: Chemical Abstracts Service
CE: Conformite Europeenne
CFR: Code of Federal Regulations
CLP: Classification, Labelling and Packaging
CNS: Central Nervous System
DMEL: Derived minimal effect level
DNEL: Derived no-effect level
EC: European Community
EN: European Standard
EQ: Excepted quantities
EU: European Union
Eye Dam.: Eye damage
GHS: Globally Harmonized System
IATA: International Air Transport Association
IATA-DGR: International Air Transport Association – Dangerous Goods Regulations
IBC Code: International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk
IMDG Code: International Maritime Dangerous Goods Code
MARPOL: Maritime Pollution: The International Convention for the Prevention of Pollution from Ships
M-factor: Multiplication factor
MS: Ministério da Saúde
NBR: Norma Brasileira
OEL: Occupational Exposure Limit Value
OSHA: Occupational Safety and Health Administration
PBT: Persistent, bioaccumulative and toxic
PNEC: Predicted no-effect concentration
RDC: Resolução da Diretoria Colegiada
RENACIAT: Rede Nacional de Centros de Informação e Assistência Toxicológica
RID: Regulations Concerning the International Carriage of Dangerous Goods by Rail
Skin Corr.: Skin corrosion
Skin Sens.: Skin sensitisation
TLV: Threshold Limit Value
TRGS: Technical Rules for Hazardous Substances
vPvB: Very persistent and very bioaccumulative
WEL: Workplace Exposure Limit