

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

### 1.1 Product identifier

Trade Name: Topkal HbA1c

Article n°: 6090XXX

MS: 80115310146

### 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 – Customer 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

### 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

Additional information: Contains Potassium cyanide < 0.008%

## 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

No data available

#### 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

Avoid breathing vapours. Wear appropriate protective equipment. Provide adequate ventilation. Avoid contact with the substance. 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, siliceous 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. Avoid breathing vapours. After worktime and during work intervals the affected skin areas must be thoroughly cleaned. Wear appropriate protective equipment. Take off contaminated clothing and wash it before reuse. Keep all containers, equipment and working place clean.

### 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 feedingsuffs.

Storage class: 12 = Non-combustible liquids

### 7.3 Specific end use(s)

No information available.

## 8 Exposure controls/personal protection

### 8.1 Control parameters

Additional information: Contains no substances with occupational exposure limit values.

### 8.2 Exposure controls

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

### Personal protection equipment

#### Occupational exposure controls

Respiratory protection: When aerosols and vapours form:  
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:  
Avoid breathing vapours. Avoid contact with skin and eyes. Take off contaminated clothing and wash it before reuse. Wash hands before breaks and after work. Provide a conveniently located eye rinse station.

### 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       |
| <b>9.2 Other information</b> |                      |
| 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 from frost, heat and sunlight.

### 10.5 Incompatible materials

Strong acids and alkalis.

### 10.6 Hazardous decomposition products

No decomposition when used properly.

|                        |                   |
|------------------------|-------------------|
| Thermal decomposition: | No data available |
|------------------------|-------------------|

## 11 Toxicological information

Toxicological effects:

|  |               |
|--|---------------|
| 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:                                    | Lack of data. |
| 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:<br>(single exposure)   | Lack of data. |
| Specific target organ toxicity:<br>(repeated exposure) | Lack of data. |
| Aspiration hazard:                                     | Lack of data. |

Endocrine disrupting properties: No data available

Other information: Contains Potassium cyanide:  
LD50 Rat, oral: 5 mg/kg

## 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

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  
 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  
 AS/NZS: Australian Standards/New Zealand Standards  
 CAS: Chemical Abstracts Service  
 CE: Conforme Europeenne  
 CFR: Code of Federal Regulations  
 CLP: Classification, Labelling and Packaging  
 DMEL: Derived minimal effect level  
 DNEL: Derived no-effect level  
 EC: European Community  
 EN: European Standard  
 EQ: Excepted quantities  
 EU: European Union  
 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  
 LD50: Lethal dose 50%  
 IMDG Code: International Maritime Dangerous Goods Code  
 MARPOL: Maritime Pollution: The International Convention for the Prevention of Pollution from Ships  
 MS: Ministério da Saúde  
 NBR: Norma Brasileira  
 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  
 TRGS: Technical Rules for Hazardous Substances  
 vPvB: Very persistent and very bioaccumulative