

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

1.1 Product identifier

Trade Name: TopKon N

Article n°: 6020XXX

MS: 80115310226

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: Lyophilisate

Additional information: The product does not contain dangerous substances above limits that need to be mentioned in this section according to applicable legislation.

4 First aid measures

4.1 Description of first aid measures

In case of inhalation: Move victim to fresh air. Seek medical treatment in case of troubles.

Following skin contact:	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 immediately and drink plenty of water. Never give anything by mouth to an unconscious person. Induce vomiting. 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

Fires in the immediate vicinity may cause the development of dangerous vapours.

5.3 Advice for firefighters

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

6 Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Wear appropriate protective equipment. Avoid contact with the substance. Do not inhale substance. Provide adequate ventilation.

6.2 Environmental precautions

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

6.3 Methods and material for containment and cleaning up

Take up mechanically, placing in appropriate containers for disposal. Clean the contaminated area with: chlorine-based bleaching agents (5%-solution) and water.

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 inhale substance. 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. Safety shower and eye wash station should be easily accessible to the work area.

7.2 Conditions for safe storage, including any incompatibilities

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

Storage class: 13 = Non-combustible solids

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: Provide adequate ventilation.

Hand protection: Protective gloves according to EN 374.
Glove material: Nitrile rubber - 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:
Take off contaminated clothing and wash it before reuse. Do not inhale substance. After worktime and during work intervals the affected skin areas must be thoroughly cleaned. Safety shower and eye wash station should be easily accessible to the work area.

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 Solid
Form: lyophilizate

Colour: White up to yellowish

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: Not applicable

Viscosity, kinematic: No data available

Water solubility: Complete soluble

Partition coefficient: n-octanol/water: No data available

Vapour pressure: No data available

Density: No data available

Vapour density: No data available

Particle characteristics: No data available

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 subsection "Possibility of hazardous reactions".

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 decomposition when used properly.

Thermal decomposition: No data available

11 Toxicological information

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: Lack of data.

(single exposure)

Specific target organ toxicity: Lack of data.

(repeated exposure)

Aspiration hazard: Lack of data.

Endocrine disrupting properties: No data available

Other information: No data available

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, ADN, IMDG, IATA-DGR Not applicable

14.2 UN proper shipping name

ADR/RID, ADN, IMDG, IATA-DGR Not restricted

14.3 Transport hazard class(es)

ADR/RID, ADN, IMDG, IATA-DGR Not applicable

14.4 Risk Number

-

14.5 Packing group

ADR/RID, ADN, 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 - IMDG: 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 Européenne
 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
 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