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

1.1 Product identifier
Trade Name: Topkal HDL/LDL
Article n°: 6290XXX
MS: 80115310095

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

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
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

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: (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:	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: Conformite 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
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