

SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of: GB/T 16483-2008, GB/T 17519-2013

Product Name Lyphochek Coagulation Control, Level 3

Revision date 04-Dec-2020

Revision Number 1

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

Product identifier

Product Name Lyphochek Coagulation Control, Level 3

Catalogue Number(s) 746

Other means of identification

Pure substance/mixture Mixture

Details of the supplier of the safety data sheet

Corporate Headquarters

Bio-Rad Laboratories 1000 Alfred Nobel Drive

Hercules, CA 94547

USA

Manufacturer

Bio-Rad Laboratories, Diagnostic

Group

9500 Jeronimo Road Irvine, California 92618-2017

USA

Legal Entity / Contact Address

Bio-Rad Laboratories Ltd.

1st and 2nd Floor, Lumpini 1 Building 239/2, Rajdamri Road, Lumpini, Pathumwan, Bangkok 10330

Thailand

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Emergency telephone number

24 Hour Emergency Phone Number CHEMTREC Hong Kong: 800-968-793

Recommended use of the chemical and restrictions on use

Recommended use In vitro diagnostic

SECTION 2: Hazards identification

Emergency Overview

No significant adverse health effects

Appearance powder or cake, lyophilised Physical state Solid Odour Slight

Classification of the substance or mixture

Acute toxicity - Oral Category 5

Label elements

Signal word Warning

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Hazard statements

May be harmful if swallowed

Precautionary statements

Response

Call a POISON CENTRE or doctor if you feel unwell

Physical and chemical hazards

Not applicable.

Health hazards

Immediate Health Effects: If large quantities of this material are swallowed, call a doctor immediately. If symptoms persist, call a

doctor.

Chronic effects: Not applicable.

Environmental hazards

Not applicable

Other hazards which do not result in classification

Not applicable

Contains human source material and / or potentially infectious components.

SECTION 3: Composition/information on ingredients

Substance

Not applicable.

Mixture

Chemical name	Weight-%	CAS No
Trade secret	10 - 20	-

SECTION 4: First aid measures

Description of necessary first aid measures

General advice No hazards which require special first aid measures.

Inhalation Remove to fresh air.

Eye contact Contains human source material and / or potentially infectious components. Call a doctor.

Skin contact Wash skin with soap and water.

Ingestion Call a doctor. Contains human source material and / or potentially infectious components.

Most important symptoms and effects, both acute and delayed

No information available.

For emergency responders No information available.

Note to doctorsContains human source material and / or potentially infectious components.

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SECTION 5: Firefighting measures

Extinguishing media

surrounding environment.

Unsuitable extinguishing media No information available.

Specific hazards arising from the

<u>chemical</u>

No information available.

Special protective actions for

fire-fighters

Firefighters should wear self-contained breathing apparatus and full firefighting turnout

gear. Use personal protection equipment.

SECTION 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures

Personal precautions See section 8 for more information.

Environmental precautions See Section 12 for additional Ecological Information.

Methods and material for containment and cleaning up

Do not allow into any sewer, on the ground or into any body of water. Clean contaminated

surface thoroughly. Use:. Disinfectant.

Precautions to prevent secondary

<u>hazards</u>

Clean contaminated objects and areas thoroughly observing environmental regulations.

SECTION 7: Handling and storage

<u>Precautions for safe handling</u> Handle in accordance with good industrial hygiene and safety practice. Follow universal

and standard precautions for handling potentially infectious materials. See Section 8 for

information on appropriate personal protective equipment.

Conditions for safe storage, including any incompatibilities

Store according to product and label instructions.

Incompatible materialsNone known based on information supplied.

SECTION 8: Exposure controls/personal protection

Occupational exposure limits

This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

Note See section 16 for terms and abbreviations

Biological occupational exposure limits

This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific

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regulatory bodies

Monitoring and observation processes

No applicable information was found.

Engineering controls Showers

Eyewash stations Ventilation systems.

Individual protection measures, such as personal protective equipment

Eye/face protection Wear safety glasses with side shields (or goggles).

Skin and body protectionWear suitable protective clothing.

Hand protection Wear suitable gloves.

exceeded or irritation is experienced, ventilation and evacuation may be required.

General hygiene considerations Follow universal and standard precautions for handling potentially infectious materials.

SECTION 9: Physical and chemical properties

Information on basic physical and chemical properties

Appearance powder or cake, lyophilised

Colour light yellow Physical state Solid Odour Slight

Odour threshold No information available

Property Values Remarks • Method

pH 6.75-6.85

No data available Melting point / freezing point None known Boiling point / boiling range No data available Not applicable Flash point No data available Not applicable **Evaporation rate** No data available None known No data available Flammability (solid, gas) None known Flammability Limit in Air None known

Upper flammability or explosive No data available

limits

Lower flammability or explosive No data available

limits

Vapour pressure
Vapour density
No data available
None known

Relative density
Water solubility
Soluble in water
No data available
No data available

Solubility(ies) No data available None known Partition coefficient No data available None known **Autoignition temperature** No data available None known **Decomposition temperature** No data available None known Kinematic viscosity No data available None known No data available **Dynamic viscosity** None known

Additional information

Explosive properties Not applicable Oxidising properties Not applicable

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SECTION 10: Stability and reactivity

<u>Stability</u> Stable under normal conditions.

Possibility of hazardous reactions None under normal processing.

Sensitivity to mechanical impact None. Sensitivity to static discharge None.

<u>Conditions to avoid</u> None known based on information supplied.

Incompatible materialsNone known based on information supplied.

Hazardous decomposition products None known based on information supplied.

SECTION 11: Toxicological information

Acute toxicity

Numerical measures of toxicity

The following values are calculated based on chapter 3.1 of the GHS document

ATEmix (oral) 2,406.40 mg/kg ATEmix (dermal) 10,034.70 mg/kg

Unknown acute toxicity

69.294 % of the mixture consists of ingredient(s) of unknown acute oral toxicity

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Trade secret	> 2000 mg/kg (Rat)	-	-

Skin corrosion/irritation

Based on available data, the classification criteria are not met.

Serious eye damage/eye irritation

Based on available data, the classification criteria are not met.

Based on available data, the classification criteria are not met.

Based on available data, the classification criteria are not met.

Carcinogenicity

Based on available data, the classification criteria are not met.

Based on available data, the classification criteria are not met.

Reproductive toxicity Based on available data, the classification criteria are not met.

Specific target organ toxicity — single exposure

Based on available data, the classification criteria are not met.

Specific target organ toxicity — repeated exposure

Based on available data, the classification criteria are not met.

Aspiration hazard Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

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Ecotoxicity

Unknown aquatic toxicity 0.001 % of the mixture consists of component(s) of unknown hazards to the aquatic

environment

Chemical name	Algae/aquatic plants	Fish	Crustacea
Trade secret	-	LC50: >100mg/L (96h, Danio	-
		rerio)	

<u>Persistence and degradability</u> No information available.

<u>Bioaccumulative potential</u> No information available.

Mobility in soil No information available.

SECTION 13: Disposal considerations

<u>Waste chemicals</u> Dispose of in accordance with local regulations. Dispose of waste in accordance with

environmental legislation.

Contaminated packaging Do not reuse empty containers.

SECTION 14: Transport information

IMDG Not regulated

Transport in bulk according to No information available

Annex II of MARPOL and the IBC

Code

IATA Not regulated

<u>China</u> Not regulated

Special precautions for user

Please refer to the applicable dangerous goods regulations for additional information

SECTION 15: Regulatory information

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

National regulations

Law of the People's Republic of China on Prevention and Control of Occupational Diseases

Catalogue of occupational hazard factors:

Catalogue of occupational diseases:

Not applicable.

Not applicable.

Regulations on the Control over Safety of Hazardous Chemicals

<u>Inventory of hazardous chemicals</u>

Not applicable.

GB 18218-2009 Identification of major hazard installations for dangerous chemicals Not applicable

List of hazardous chemicals under priority management

Not applicable

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Regulations on Labour Protection in Workplaces Where Toxic Substances Are Used

Inventory of highly toxic goods Not applicable

Regulations for Environmental Management on the First Import of Chemicals and the Import and Export of Toxic Chemicals

List of toxic chemicals severely restricted for import and export in China Not applicable

Measures for the Environmental Management of New Chemical Substances

IECSC - China Inventory of Existing Chemical SubstancesContact supplier for inventory compliance status.

International Regulations

The Montreal Protocol on Substances that Deplete the Ozone Layer Not applicable

The Stockholm Convention on Persistent Organic Pollutants Not applicable

The Rotterdam Convention Not applicable

SECTION 16: Other information

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Revision Note*** Indicates this information has changed since the previous revision.

Abbreviations and acronyms

Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

TWA TWA (time-weighted average) STEL STEL (Short Term Exposure Limit)

Ceiling Maximum limit value * Skin designation

C Carcinogen

Key literature references and sources for data used to compile the SDS

Agency for Toxic Substances and Disease Registry (ATSDR) U.S. Environmental Protection Agency ChemView Database

European Food Safety Authority (EFSA) EPA (Environmental Protection Agency)

Acute Exposure Guideline Level(s) (AEGL(s))

U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act

U.S. Environmental Protection Agency High Production Volume Chemicals

Food Research Journal

Hazardous Substance Database

International Uniform Chemical Information Database (IUCLID)

Japan GHS Classification

Australian National Industrial Chemicals Notification and Assessment Scheme (NICNAS)

NIOSH (National Institute for Occupational Safety and Health)

National Library of Medicine's ChemID Plus (NLM CIP)

National Library of Medicine's PubMed database (NLM PUBMED)

National Toxicology Program (NTP)

New Zealand's Chemical Classification and Information Database (CCID)

Organisation for Economic Co-operation and Development Environment, Health, and Safety Publications Organisation for Economic Co-operation and Development High Production Volume Chemicals Programme

Organisation for Economic Co-operation and Development Screening Information Data Set

RTECS (Registry of Toxic Effects of Chemical Substances)

World Health Organization

Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the

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date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text

End of Safety Data Sheet

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