



# SAFETY DATA SHEET

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

### Recommended use of the chemical and restrictions on use

**Recommended use** In vitro diagnostic

**Uses advised against** No information available

### 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 Pty Ltd  
189 Bush Road  
Albany Auckland  
New Zealand

**Technical Service** +64 9 415 2280 or 0508 805 500  
sales.nz@bio-rad.com

### Emergency telephone number

**24 Hour Emergency Phone Number** CHEMTREC New Zealand: 64-98010034

## SECTION 2: Hazards identification

### GHS Classification

<b>Acute toxicity - Oral</b>	Category 5 (HSNO - 6.1E)
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### Label elements

#### **Signal word**

Warning

#### **Hazard statements**

H303 - May be harmful if swallowed

### Other hazards which do not result in classification

Contains human source material and / or potentially infectious components

## SECTION 3: Composition/information on ingredients

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

Non-hazardous ingredients	Proprietary	Balance
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## SECTION 4: First aid measures

### Description of 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

Symptoms	No information available.
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### Indication of any immediate medical attention and special treatment needed

Note to doctors	Contains human source material and / or potentially infectious components.
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## SECTION 5: Firefighting measures

### Suitable Extinguishing Media

Suitable Extinguishing Media	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
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Unsuitable extinguishing media	No information available.
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### Specific hazards arising from the chemical

Specific hazards arising from the chemical	None known.
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### Special protective actions for fire-fighters

Special protective equipment for fire-fighters	Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.
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## SECTION 6: Accidental release measures

### Personal precautions, protective equipment and emergency procedures

Personal precautions	See section 8 for more information.
For emergency responders	Use personal protection recommended in Section 8.

### Environmental precautions

**Environmental precautions** See Section 12 for additional Ecological Information.

**Methods and material for containment and cleaning up**

**Methods for containment** Do not allow into any sewer, on the ground or into any body of water.

**Methods for cleaning up** Clean contaminated surface thoroughly. Use: Disinfectant.

**Precautions to prevent secondary hazards**

**Prevention of secondary hazards** Clean contaminated objects and areas thoroughly observing environmental regulations.

## **SECTION 7: Handling and storage**

**Precautions for safe handling**

**Advice on safe handling** Handle in accordance with good industrial hygiene and safety practice.

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

**Conditions for safe storage, including any incompatibilities**

**Storage Conditions** Store according to product and label instructions.

**Incompatible materials** None known based on information supplied.

## **SECTION 8: Exposure controls/personal protection**

**Control parameters**

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

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

**Appropriate engineering controls**

**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).

**Hand protection** Wear suitable gloves.

**Skin and body protection** Wear suitable protective clothing.

**Respiratory protection** No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.

**Environmental exposure controls** No information available.

## SECTION 9: Physical and chemical properties

### Information on basic physical and chemical properties

<b>Physical state</b>	Solid
<b>Appearance</b>	powder or cake, lyophilised
<b>Colour</b>	light yellow
<b>Odour</b>	Slight.
<b>Odour threshold</b>	No information available

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
<b>pH</b>	6.75-6.85	
<b>Melting point / freezing point</b>	No data available	None known
<b>Boiling point / boiling range</b>	No data available	Not applicable
<b>Flash point</b>	No data available	Not applicable
<b>Evaporation rate</b>	No data available	None known
<b>Flammability (solid, gas)</b>	No data available	None known
<b>Flammability Limit in Air</b>		None known
<b>Upper flammability or explosive limits</b>	No data available	
<b>Lower flammability or explosive limits</b>	No data available	
<b>Vapour pressure</b>	No data available	None known
<b>Vapour density</b>	No data available	None known
<b>Relative density</b>	No data available	None known
<b>Water solubility</b>	Soluble in water	
<b>Solubility(ies)</b>	No data available	None known
<b>Partition coefficient</b>	No data available	None known
<b>Autoignition temperature</b>	No data available	None known
<b>Decomposition temperature</b>		None known
<b>Kinematic viscosity</b>	No data available	None known
<b>Dynamic viscosity</b>	No data available	None known
<b>Explosive properties</b>	Not applicable.	
<b>Oxidising properties</b>	Not applicable.	
<b>Other information</b>		
<b>Molecular weight</b>	Not applicable	
<b>VOC Content (%)</b>	Not applicable	

## SECTION 10: Stability and reactivity

### Reactivity

**Reactivity** No information available.

### Chemical stability

**Stability** Stable under normal conditions.

### Explosion data

**Sensitivity to mechanical impact** None.

**Sensitivity to static discharge** None.

### Possibility of hazardous reactions

**Possibility of hazardous reactions** None under normal processing.

**Conditions to avoid**

**Conditions to avoid** None known based on information supplied.

**Incompatible materials**

**Incompatible materials** None known based on information supplied.

**Hazardous decomposition products**

**Hazardous decomposition products** None known based on information supplied.

**SECTION 11: Toxicological information****Acute toxicity****Information on likely routes of exposure****Product Information**

**Inhalation** Specific test data for the substance or mixture is not available.

**Eye contact** Specific test data for the substance or mixture is not available.

**Skin contact** Specific test data for the substance or mixture is not available.

**Ingestion** May be harmful if swallowed.

**Symptoms** No information available.

**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

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

**Delayed and immediate effects as well as chronic effects from short and long-term exposure**

**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.

**Germ cell mutagenicity** Based on available data, the classification criteria are not met.

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

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

**STOT - single exposure** Based on available data, the classification criteria are not met.

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

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

**STOT - 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

### Ecotoxicity

**Ecotoxicity** .

### **Aquatic 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)	-

**Terrestrial ecotoxicity** There is no data for this product.

**Persistence and degradability** No information available.

### Bioaccumulative potential

**Bioaccumulation** No information available.

### Mobility in soil

### Other adverse effects

No information available.

## SECTION 13: Disposal considerations

### Waste treatment methods

**Contaminated packaging** For packages that have been in direct contact with hazardous substances, the person must ensure that the package is rendered incapable of containing any substance. It must be disposed of in a manner that is consistent with the requirements for disposal of the substance that it contained, taking into account the material the package is manufactured from.  
Packages may only be reused or recycled if the package has been treated to remove any residual contents of the hazardous substance (class 1, 2, 3, 4, or 5); or the contents of the residue in the package are below the threshold for the substance to be classified as hazardous (class 6, 8, or 9 substance)

## SECTION 14: Transport information

**IATA** Not regulated

**IMDG** Not regulated

**Transport in bulk according to Annex II of MARPOL and the IBC Code**  
No information available

## SECTION 15: Regulatory information

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

#### National regulations

##### New Zealand

#### National regulations

See Section 8 for any applicable tolerable exposure limits and environmental exposure limits

#### Certified handlers, tracking and controlled substance license requirements

Certified handlers are required for some substances. This includes for substances requiring a controlled substance license, including Class 1 explosives, vertebrate toxic agents (9.3A, B, C), and certain fumigants. Class 6.1A and 6.1B substances such as pesticides also require Certified handlers. Please check the Health and Safety at Work Act 2015 for further information

Tracking is required for some highly hazardous substances. These substances need to be under the control of an appropriately trained person or appropriately secured. Please check the Health and Safety at Work Act 2015 for further information

Controlled substance licenses are required to possess certain class 1 (explosive) and class 6 (vertebrate toxic agents or fumigants) substances. See Part 7 of the Health and Safety at Work Regulation 2017 for more information

#### EPA New Zealand HSNO approval code or group standard

Not applicable

#### International Inventories

Contact supplier for inventory compliance status

#### Legend:

#### 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

#### Prepared By

Bio-Rad Laboratories, Environmental Health and Safety

#### Revision date

04-Dec-2020

#### Revision Note

\*\*\* Indicates this information has changed since the previous revision.

#### Key or legend to abbreviations and acronyms used in the safety data sheet

##### 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**

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**End of Safety Data Sheet**