



# SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of:  
Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision 04-Dec-2020  
date

Previous revision 18-Sep-2020  
date

Revision Number 1

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

### 1.1. Product identifier

Product Name Lyphochek Coagulation Control, Level 3

Catalogue Number(s) 746

Pure substance/mixture Mixture

### 1.2. Relevant identified uses of the substance or mixture and uses advised against

Recommended use In vitro diagnostic

### 1.3. 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  
The Junction  
Station Road  
Watford, WD17 1ET  
UK

For further information, please contact

Technical Service 00800 00246 723  
Techsupport.UK@bio-rad.com

### 1.4. Emergency telephone number

24 Hour Emergency Phone Number CHEMTREC UK: 44-870-8200418

Austria	+43 1 406 43 43
Sweden	+112

## SECTION 2: Hazards identification

### 2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008

This mixture is classified as not hazardous according to regulation (EC) 1272/2008 [GHS]

### 2.2. Label elements

This mixture is classified as not hazardous according to regulation (EC) 1272/2008 [GHS]

#### Hazard statements

This mixture is classified as not hazardous according to regulation (EC) 1272/2008 [GHS]

EUH210 - Safety data sheet available on request

### 2.3. Other hazards

Contains human source material and / or potentially infectious components

**SECTION 3: Composition/information on ingredients****3.1 Substances**

Not applicable

**3.2 Mixtures**

The product contains no substances which at their given concentration, are considered to be hazardous to health

**Full text of H- and EUH-phrases: see section 16**

**SECTION 4: First aid measures****4.1. Description of first aid measures**

<b>General advice</b>	No hazards which require special first aid measures.
<b>Inhalation</b>	Remove to fresh air.
<b>Eye contact</b>	Contains human source material and / or potentially infectious components. Call a doctor.
<b>Skin contact</b>	Wash skin with soap and water.
<b>Ingestion</b>	Call a doctor. Contains human source material and / or potentially infectious components.

**4.2. Most important symptoms and effects, both acute and delayed**

<b>Symptoms</b>	No information available.
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**4.3. Indication of any immediate medical attention and special treatment needed**

<b>Note to doctors</b>	Contains human source material and / or potentially infectious components.
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**SECTION 5: Firefighting measures****5.1. Extinguishing media**

<b>Suitable Extinguishing Media</b>	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
<b>Unsuitable extinguishing media</b>	No information available.

**5.2. Special hazards arising from the substance or mixture**

<b>Specific hazards arising from the chemical</b>	None known.
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**5.3. Advice for firefighters**

<b>Special protective equipment for fire-fighters</b>	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****6.1. Personal precautions, protective equipment and emergency procedures**

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

**6.2. Environmental precautions**

<b>Environmental precautions</b>	See Section 12 for additional Ecological Information.
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**6.3. Methods and material for containment and cleaning up**

<b>Methods for containment</b>	Do not allow into any sewer, on the ground or into any body of water.
<b>Methods for cleaning up</b>	Clean contaminated surface thoroughly. Use: Disinfectant.
<b>Prevention of secondary hazards</b>	Clean contaminated objects and areas thoroughly observing environmental regulations.

**6.4. Reference to other sections**

<b>Reference to other sections</b>	See section 8 for more information. See section 13 for more information.
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**SECTION 7: Handling and storage****7.1. Precautions for safe handling**

<b>Advice on safe handling</b>	Ensure adequate ventilation.
<b>General hygiene considerations</b>	Follow universal and standard precautions for handling potentially infectious materials.

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

<b>Storage Conditions</b>	Store according to product and label instructions.
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**7.3. Specific end use(s)**

<b>Risk Management Methods (RMM)</b>	The information required is contained in this Safety Data Sheet.
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**SECTION 8: Exposure controls/personal protection****8.1. Control parameters**

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

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

<b>Derived No Effect Level (DNEL)</b>	No information available.
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<b>Predicted No Effect Concentration (PNEC)</b>	No information available.
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**8.2. Exposure controls****Personal protective equipment**

<b>Eye/face protection</b>	Wear safety glasses with side shields (or goggles).
<b>Hand protection</b>	Wear suitable gloves.
<b>Skin and body protection</b>	Wear suitable protective clothing.
<b>Respiratory protection</b>	No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.
<b>General hygiene considerations</b>	Follow universal and standard precautions for handling potentially infectious materials.
<b>Environmental exposure controls</b>	No information available.

**SECTION 9: Physical and chemical properties****9.1. 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

<b>Property</b>	<b>Values</b>	<b>Remarks • Method</b>
<b>pH</b>	6.75-6.85	
<b>pH (as aqueous solution)</b>		
<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	

**9.2. Other information**

<b>Softening point</b>	Not applicable
<b>Molecular weight</b>	Not applicable
<b>VOC Content (%)</b>	Not applicable

**SECTION 10: Stability and reactivity****10.1. Reactivity**

**Reactivity** No information available.

**10.2. Chemical stability**

**Stability** Stable under normal conditions.

**Explosion data**

**Sensitivity to mechanical impact** None.

**Sensitivity to static discharge** None.

**10.3. Possibility of hazardous reactions**

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

**10.4. Conditions to avoid**

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

**10.5. Incompatible materials**

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

**10.6. Hazardous decomposition products**

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

**SECTION 11: Toxicological information****11.1. Information on toxicological effects****Information on likely routes of exposure****Product Information**

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

**Symptoms related to the physical, chemical and toxicological characteristics**

**Symptoms** No information available.

**Numerical measures of toxicity****Acute 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

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

<b>Skin corrosion/irritation</b>	Based on available data, the classification criteria are not met.
<b>Serious eye damage/eye irritation</b>	Based on available data, the classification criteria are not met.
<b>Respiratory or skin sensitisation</b>	Based on available data, the classification criteria are not met.
<b>Germ cell mutagenicity</b>	Based on available data, the classification criteria are not met.
<b>Carcinogenicity</b>	Based on available data, the classification criteria are not met.
<b>Reproductive toxicity</b>	Based on available data, the classification criteria are not met.
<b>STOT - single exposure</b>	Based on available data, the classification criteria are not met.
<b>STOT - repeated exposure</b>	Based on available data, the classification criteria are not met.
<b>Aspiration hazard</b>	Based on available data, the classification criteria are not met.

**SECTION 12: Ecological information****12.1. Toxicity**

<b>Ecotoxicity</b>	.
<b>Unknown aquatic toxicity</b>	Contains 0.001 % of components with unknown hazards to the aquatic environment.

**12.2. Persistence and degradability**

<b>Persistence and degradability</b>	No information available.
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**12.3. Bioaccumulative potential**

<b>Bioaccumulation</b>	No information available.
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**12.4. Mobility in soil**

<b>Mobility in soil</b>	No information available.
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**12.5. Results of PBT and vPvB assessment**

<b>PBT and vPvB assessment</b>	The product contains substance(s) classified as PBT or vPvB.
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**12.6. Other adverse effects**

<b>Other adverse effects</b>	No information available.
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**SECTION 13: Disposal considerations****13.1. Waste treatment methods**

<b>Waste from residues/unused products</b>	Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.
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Contaminated packaging

Do not reuse empty containers.

**SECTION 14: Transport information****IMDG**

14.1 UN number or ID number	Not regulated
14.2 UN proper shipping name	Not regulated
14.3 Transport hazard class(es)	Not regulated
14.4 Packing group	Not regulated
14.5 Marine pollutant	Not applicable
14.6 Special Precautions for Users	
Special Provisions	None
14.7. Transport in bulk according to Annex II of MARPOL and the IBC Code	No information available

**RID**

14.1 UN number	Not regulated
14.2 UN proper shipping name	Not regulated
14.3 Transport hazard class(es)	Not regulated
14.4 Packing group	Not regulated
14.5 Environmental hazards	Not applicable
14.6 Special Precautions for Users	
Special Provisions	None

**ADR**

14.1 UN number	Not regulated
14.2 UN proper shipping name	Not regulated
14.3 Transport hazard class(es)	Not regulated
14.4 Packing group	Not regulated
14.5 Environmental hazards	Not applicable
14.6 Special Precautions for Users	
Special Provisions	None

**IATA**

14.1 UN number	Not regulated
14.2 UN proper shipping name	Not regulated
14.3 Transport hazard class(es)	Not regulated
14.4 Packing group	Not regulated
14.5 Environmental hazards	Not applicable
14.6 Special Precautions for Users	
Special Provisions	None

**SECTION 15: Regulatory information****15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture****National regulations****Germany**

Water hazard class (WGK) slightly hazardous to water (WGK 1)

**European Union**

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents

at work

#### Authorisations and/or restrictions on use:

This product does not contain substances subject to authorisation (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

#### Persistent Organic Pollutants

Not applicable

**Ozone-depleting substances (ODS) regulation (EC) 1005/2009** Not applicable

#### International Inventories

Contact supplier for inventory compliance status

### 15.2. Chemical safety assessment

#### Chemical Safety Report

No information available

## SECTION 16: Other information

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

#### Legend

SVHC: Substances of Very High Concern for Authorisation:

#### Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

TWA	TWA (time-weighted average)	STEL	STEL (Short Term Exposure Limit)
Ceiling	Maximum limit value	*	Skin designation

Classification procedure	
Classification according to Regulation (EC) No. 1272/2008 [CLP]	Method Used
Acute oral toxicity	Calculation method
Acute dermal toxicity	Calculation method
Acute inhalation toxicity - gas	Calculation method
Acute inhalation toxicity - Vapour	Calculation method
Acute inhalation toxicity - dust/mist	Calculation method
Skin corrosion/irritation	Calculation method
Serious eye damage/eye irritation	Calculation method
Respiratory sensitisation	Calculation method
Skin sensitisation	Calculation method
Mutagenicity	Calculation method
Carcinogenicity	Calculation method
Reproductive toxicity	Calculation method
STOT - single exposure	Calculation method
STOT - repeated exposure	Calculation method
Acute aquatic toxicity	Calculation method
Chronic aquatic toxicity	Calculation method
Aspiration hazard	Calculation method
Ozone	Calculation method

### 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) (AELG(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

**Prepared By** Bio-Rad Laboratories, Environmental Health and Safety

**Revision date** 04-Dec-2020

**Reason for revision** \*\*\* Indicates this information has changed since the previous revision

**This material safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006**

**Disclaimer**

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