



# 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 date 13-Apr-2021 Previous revision date 18-Sep-2020 Revision Number 1

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

### 1.1. Product identifier

Product Name Lyphochek Diabetes Control

Catalogue Number(s) 740, 740X

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 Inc.  
1000 Alfred Nobel Drive  
Hercules, CA 94547  
USA

#### Manufacturer

Bio-Rad Laboratories Inc.  
9500 Jeronimo Road  
Irvine, California 92618  
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

## 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 [CLP]

### 2.2. Label elements

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

#### Hazard statements

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

### 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. |
|-----------------|---------------------------|

### **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. |
|------------------------|--|

## **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. |
|---|-------------|

### **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. |
|---|--|

## **SECTION 6: Accidental release measures**

### **6.1. Personal precautions, protective equipment and emergency procedures**

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|                                 |   |
|---------------------------------|---|
| <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. |
|----------------------------------|---|

#### **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. |
|------------------------------------|--|

### **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. |
|---------------------------|--|

#### **7.3. Specific end use(s)**

|                                      |  |
|--------------------------------------|--|
| <b>Risk Management Methods (RMM)</b> | The information required is contained in this Safety Data Sheet. |
|--------------------------------------|--|

### **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. |
|------------------------|---|

#### **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. |
|---------------------------------------|---------------------------|

|   |                           |
|---|---------------------------|
| <b>Predicted No Effect Concentration (PNEC)</b> | No information available. |
|---|---------------------------|

#### **8.2. Exposure controls**

##### **Personal protective equipment**

|                            |   |
|----------------------------|---|
| <b>Eye/face protection</b> | Wear safety glasses with side shields (or goggles). |
|----------------------------|---|

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|  |  |
|--|--|
| <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>          | red                         |
| <b>Odour</b>           | Slight.                     |
| <b>Odour threshold</b> | No information available    |

| <u>Property</u>                        | <u>Values</u>     | <u>Remarks • Method</u> |
|--|-------------------|-------------------------|
| pH                                     | 7.95-8.05         |                         |
| pH (as aqueous solution)               |                   |                         |
| Melting point / freezing point         | No data available | None known              |
| Boiling point / boiling range          | No data available | None known              |
| Flash point                            | No data available | None known              |
| Evaporation rate                       | No data available | None known              |
| Flammability (solid, gas)              | No data available | None known              |
| Flammability Limit in Air              |                   | None known              |
| Upper flammability or explosive limits | No data available |                         |
| Lower flammability or explosive limits | No data available |                         |
| Vapour pressure                        | No data available | None known              |
| Vapour density                         | No data available | None known              |
| Relative density                       | No data available | None known              |
| Water solubility                       | Soluble in water  |                         |
| Solubility(ies)                        | No data available | None known              |
| Partition coefficient                  | No data available | None known              |
| Autoignition temperature               | No data available | None known              |
| Decomposition temperature              |                   | None known              |
| Kinematic viscosity                    | No data available | None known              |
| Dynamic viscosity                      | No data available | None known              |
| Explosive properties                   | Not applicable    |                         |
| Oxidising properties                   | 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**

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**

##### 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.

Respiratory or skin sensitisation 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. |
| 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

### 12.1. Toxicity

|                          |   |
|--------------------------|---|
| Ecotoxicity              | .   |
| Unknown aquatic toxicity | Contains 0 % of components with unknown hazards to the aquatic environment. |

### 12.2. Persistence and degradability

|                               |                           |
|-------------------------------|---------------------------|
| Persistence and degradability | No information available. |
|-------------------------------|---------------------------|

### 12.3. Bioaccumulative potential

|                 |                           |
|-----------------|---------------------------|
| Bioaccumulation | No information available. |
|-----------------|---------------------------|

### 12.4. Mobility in soil

|                  |                           |
|------------------|---------------------------|
| Mobility in soil | No information available. |
|------------------|---------------------------|

### 12.5. Results of PBT and vPvB assessment

|                         |                          |
|-------------------------|--------------------------|
| PBT and vPvB assessment | No information available |
|-------------------------|--------------------------|

### 12.6. Other adverse effects

|                       |                           |
|-----------------------|---------------------------|
| Other adverse effects | No information available. |
|-----------------------|---------------------------|

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

|                                     |   |
|-------------------------------------|---|
| Waste from residues/unused products | 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

|  |                          |
|--|--------------------------|
| 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 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)  
Ceiling Maximum limit value

STEL  
\*

STEL (Short Term Exposure Limit)  
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) (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

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

**Revision date** 13-Apr-2021

**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**