



# 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 28-Jul-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 Allergen sIgE Control, Negative  
**Catalogue Number(s)** 12000141, 12000143

**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**

Chemical name	EC No	CAS No	Weight-%	Classification according to Regulation (EC) No. 1272/2008 [CLP]	REACH registration number
Trade secret	.?	-	5 - 10	No data available	No data available

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

This product does not contain candidate substances of very high concern at a concentration  $\geq 0.1\%$  (Regulation (EC) No. 1907/2006 (REACH), Article 59).

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

General advice	No hazards which require special first aid measures.
Inhalation	Remove to fresh air.
Eye contact	Call a physician.
Skin contact	Wash skin with soap and water.
Ingestion	Call a physician.

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

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

Note to physicians	Treat symptomatically.
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**SECTION 5: Firefighting measures****5.1. Extinguishing media**

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

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

Specific hazards arising from the chemical	None known.
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**5.3. Advice for firefighters**

Special protective equipment and precautions 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

### 6.1. 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.

### 6.2. Environmental precautions

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

### 6.3. Methods and material for containment and cleaning up

**Methods for containment** Prevent further leakage or spillage if safe to do so.

**Methods for cleaning up** Clean contaminated surface thoroughly.

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

### 6.4. Reference to other sections

**Reference to other sections** See section 8 for more information. See section 13 for more information.

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

**Advice on safe handling** Ensure adequate ventilation.

**General hygiene considerations** Handle in accordance with good industrial hygiene and safety practice.

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

**Storage Conditions** Keep container tightly closed in a dry and well-ventilated place.

### 7.3. Specific end use(s)

#### Identified uses

**Risk Management Methods (RMM)** The information required is contained in this Safety Data Sheet.

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

#### Exposure Limits

Chemical name	European Union	United Kingdom	France	Spain	Germany
Trade secret	-	TWA: 10 mg/m <sup>3</sup> STEL: 20 mg/m <sup>3</sup>	TWA: 10 mg/m <sup>3</sup>	TWA: 10 mg/m <sup>3</sup>	-
Chemical name	Italy	Portugal	Netherlands	Finland	Denmark
Trade secret	-	TWA: 10 mg/m <sup>3</sup>	-	-	-
Chemical name	Austria	Switzerland	Poland	Norway	Ireland
Trade secret	-	-	-	-	TWA: 10 mg/m <sup>3</sup> STEL: 20 mg/m <sup>3</sup>

#### Biological occupational exposure limits

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

**Derived No Effect Level (DNEL)** No information available.

**Predicted No Effect Concentration (PNEC)** No information available.

## 8.2. Exposure controls

### 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.

**General hygiene considerations** Handle in accordance with good industrial hygiene and safety practice.

**Environmental exposure controls** No information available.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

**Physical state** Solid  
**Appearance** powder or cake, lyophilised  
**Colour** amber  
**Odour** Odourless.  
**Odour threshold** No information available

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
pH	6.9-7.5	
pH (as aqueous solution)	No data available	
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
<b>9.2. Other information</b>		
Softening point	Not applicable	
Molecular weight	Not applicable	
VOC Content (%)	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) 7,046.80 mg/kg  
ATEmix (dermal) 10,226.70 mg/kg

#### Component Information

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Trade secret	= 29700 mg/kg ( Rat )		

#### 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 sensitization</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>	Classification not possible.

## 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 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 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 Environmental hazards Not applicable

14.6 Special Precautions for Users  
Special Provisions None

### IATA

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 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)** obviously hazardous to water (WGK 2)

**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

**Authorizations and/or restrictions on use:**

This product does not contain substances subject to authorization (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** 28-Jul-2021

**Reason for revision** Significant changes throughout SDS. Review all sections

**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**