SAFETY DATA SHEET

Revision date 18-Oct-2024 **Revision Number** 1.1

1. Identification

Product identifier

Product Name Lyphochek Immunoassay Plus Control

Other means of identification

Catalog Number(s) 370, 371, 372, 373, 370X

Recommended use of the chemical and restrictions on use

Recommended use In vitro diagnostic

Details of the supplier of the safety data sheet

Corporate Headquarters	Manufacturer Address	Legal Entity / Contact Address
Bio-Rad Laboratories Inc. 1000 Alfred Nobel Drive Hercules, CA 94547 USA	Bio-Rad Laboratories Inc. 9500 Jeronimo Road Irvine, California 92618 USA	Bio-Rad Laboratories Inc. 9500 Jeronimo Road Irvine, California 92618 USA

Technical Service 1(800) 854-6737
qsd.techservice@bio-rad.com

Emergency telephone number

24 Hour Emergency Phone Number CHEMTREC USA: 1 (800) 424-9300

2. Hazard(s) identification

Classification

This chemical is not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200).

Hazards not otherwise classified (HNOC)
Not applicable

Label elements

Hazard statements
This chemical is not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200).

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

Appearance powder or cake, lyophilized **Physical state** Solid **Odor** Slight

Other information

Contains animal source material. (Cattle).
Contains human source material and / or potentially infectious components

3. Composition/information on ingredients

Substance

Not applicable.

Mixture

Chemical name	CAS No.	Weight-%	Trade secret
Sucrose	57-50-1	10 - 20	*

*The exact percentage (concentration) of composition has been withheld as a trade secret.

4. First-aid measures

Description of first aid measures

Inhalation Remove to fresh air.

Eye contact Contains human source material and / or potentially infectious components. Call a physician. Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes.

Skin contact Wash with soap and water.

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

Most important symptoms and effects, both acute and delayed

Symptoms No information available.

Indication of any immediate medical attention and special treatment needed

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

5. Fire-fighting measures

Suitable Extinguishing Media Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Specific hazards arising from the chemical No information available.

Explosion data
Sensitivity to mechanical impact None.

Sensitivity to static discharge None.

Special protective equipment and Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear.

precautions for fire-fighters Use personal protection equipment.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Personal precautions Ensure adequate ventilation.

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 Use:. Disinfectant. Clean contaminated surface thoroughly.

7. Handling and storage

Precautions for safe handling

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

Conditions for safe storage, including any incompatibilities

Storage Conditions Store according to product and label instructions.

8. Exposure controls/personal protection

Control parameters

Exposure Limits

Chemical name	ACGIH TLV	OSHA PEL	NIOSH
Sucrose 57-50-1	TWA: 10 mg/m³	TWA: 15 mg/m³ total dust TWA: 5 mg/m³ respirable fraction (vacated) TWA: 15 mg/m³ total dust (vacated) TWA: 5 mg/m³ respirable fraction	TWA: 10 mg/m³ total dust TWA: 5 mg/m³ respirable dust

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.

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

9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state	Solid
Appearance	powder or cake, lyophilized
Color	amber
Odor	Slight
Odor threshold	No information available

Property	**Values**	**Remarks • Method**
pH	7.55-7.65	
Melting point / freezing point	No data available	None known
Initial boiling point and boiling range	No data available	None known
Flash point	No data available	None known
Evaporation rate	No data available	None known
Flammability	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	
Vapor pressure	No data available	None known
Relative vapor 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	
Decomposition temperature	No data available	None known
Kinematic viscosity	No data available	None known
Dynamic viscosity	No data available	None known

Other information

Explosive properties	No information available
Oxidizing properties	No information available
Softening point	No information available
Molecular weight	No information available
VOC content	No information available
Liquid Density	No information available
Bulk density	No information available

10. Stability and reactivity

Reactivity No information available.

Chemical stability Stable under normal conditions.

Possibility of hazardous reactions Avoid contact with metals. This product contains sodium azide. Sodium azide can react with copper, brass, lead, and solder in piping systems to form explosive compounds and toxic gases.

Conditions to avoid None known based on information supplied.

Incompatible materials Metals.

Hazardous decomposition products None known based on information supplied.

11. Toxicological information

Information on likely routes of exposure

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.

Acute toxicity

Numerical measures of toxicity

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

ATEmix (oral) 101,808.00 mg/kg

Component Information

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Sucrose 57-50-1	= 29700 mg/kg (Rat)	-	-

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

Skin corrosion/irritation No information available.

Serious eye damage/eye irritation No information available.

Respiratory or skin sensitization No information available.

Germ cell mutagenicity No information available.

Carcinogenicity No information available.

Reproductive toxicity No information available.

STOT - single exposure	No information available.
STOT - repeated exposure	No information available.
Target organ effects	Respiratory system, Eyes.
Aspiration hazard	No information available.
Other adverse effects	No information available.
Interactive effects	No information available.

12. Ecological information

Ecotoxicity	The environmental impact of this product has not been fully investigated.
Persistence and degradability	No information available.
Bioaccumulation	There is no data for this product.
Other adverse effects	No information available.

13. Disposal considerations

Disposal methods

Waste from residues/unused products	Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation. Flush pipes with water frequently if discarding solutions containing sodium azide into metal piping systems.
Contaminated packaging	Do not reuse empty containers.

14. Transport information

DOT	Not regulated
TDG	Not regulated
MEX	Not regulated
IATA	Not regulated
IMDG	Not regulated

15. Regulatory information

International Inventories Contact supplier for inventory compliance status

US Federal Regulations

SARA 313
Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

SARA 311/312 Hazard Categories
Should this product meet EPCRA 311/312 Tier reporting criteria at 40 CFR 370, refer to Section 2 of this SDS for appropriate classifications.

CWA (Clean Water Act)
This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

CERCLA
This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

US State Regulations

California Proposition 65
This product contains the following Proposition 65 chemicals:.

Chemical name	California Proposition 65
Lithium carbonate - 554-13-2	Developmental
Phenobarbital - 50-06-6	Carcinogen Developmental
D-Streptamine, O-3-amino-3-deoxy-.alpha.-D-glucopyranosyl-(1->6)-O-[6-amino-6-deoxy-.alpha.-D-glucopyranosyl-(1->4)]-N1-[(2S)-4-amino-2-hydroxy-1-oxobutyl]-2-deoxy- - 37517-28-5	Developmental
Diphenylhydantoin, sodium salt - 630-93-3	Carcinogen
Carbamazepine - 298-46-4	Developmental
Primidone - 125-33-7	Carcinogen
Gentamicin, sulfate (salt) - 1405-41-0	Developmental
Tobramycin - 32986-56-4	Developmental
2-Butyl-3-benzofuryl 4-[2-(diethylamino)ethoxy]-3,5-diiodophenyl ketone hydrochloride - 19774-82-4	Developmental Female Reproductive Male Reproductive
Progesterone - 57-83-0	Carcinogen
Testosterone - 58-22-0	Carcinogen Female Reproductive Male Reproductive
Cyclosporin A - 59865-13-3	Carcinogen
Androst-4-ene-3,17-dione - 63-05-8	Carcinogen Female Reproductive Male Reproductive
Follicle-stimulating hormone - 9002-68-0	Developmental
Estradiol-17b - 50-28-2	Carcinogen

U.S. State Right-to-Know Regulations

Chemical name	New Jersey	Massachusetts	Pennsylvania
Sucrose 57-50-1	-	X	X
Sodium phosphate dibasic 7558-79-4	X	X	X
Lithium carbonate 554-13-2	X	X	-
Phenobarbital 50-06-6	-	X	-
Diphenylhydantoin, sodium salt 630-93-3	-	-	X
Chloramphenicol 56-75-7	-	X	X
Water 7732-18-5	-	-	X
Estradiol-17b 50-28-2	-	X	X
Digoxin 20830-75-5	X	X	X
Vitamin B12 68-19-9	X	-	X
Testosterone 58-22-0	-	X	X
Progesterone 57-83-0	X	X	X
Sodium azide 26628-22-8	X	X	X

U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable

16. Other information

NFPA	**Health hazards** 0	**Flammability** 1	**Instability** 0	**Special hazards** -
HMIS	**Health hazards** 0	**Flammability** 1	**Physical hazards** 0	**Personal protection** X

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	Sk*	Skin designation

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)
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)
National Institute of Technology and Evaluation (NITE)
Australia 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)
U.S. National Toxicology Program (NTP)
New Zealand's Chemical Classification and Information Database (CCID)
Organization for Economic Co-operation and Development Environment, Health, and Safety Publications
Organization for Economic Co-operation and Development High Production Volume Chemicals Program
Organization for Economic Co-operation and Development Screening Information Data Set
World Health Organization

Revision date	18-Oct-2024
Revision Note	Significant changes throughout SDS. Review all sections.

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