



SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of:
US OSHA Hazard Communication Standard (29 CFR 1910.1200)

Revision date 01-May-2025

Revision Number 2.1

1. Identification

Product identifier

Product Name Lyphocheck Therapeutic Drug Monitoring Control (TDM)

Other means of identification

Catalog Number(s) 450, 451, 452, 453, 450X

Recommended use of the chemical and restrictions on use

Recommended use In vitro diagnostic

Restrictions on use No information available

Details of the supplier of the safety data sheet

Corporate Headquarters

Bio-Rad Laboratories Inc.
1000 Alfred Nobel Drive
Hercules, CA 94547
USA

Manufacturer Address

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

Legal Entity / Contact Address

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 of the substance or mixture

This product is not considered hazardous by the US OSHA Hazard Communication Standard 2024 (29 CFR 1910.1200).

Hazards not otherwise classified (HNOC)

Not applicable

Label elements

Hazard statements

This product is not considered hazardous by the US OSHA Hazard Communication Standard 2024 (29 CFR 1910.1200).

Hazards classified under paragraph (d)(1)(ii) of 1910.1200

No information available.

Other information

Contains animal source material. (Cattle).

3. Composition/information on ingredients

Substance

Not applicable.

Mixture

Chemical name	CAS No.	Weight-%	Trade secret
Sodium chloride	7647-14-5	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.
Effects of Exposure	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.
Unsuitable extinguishing media	Do not scatter spilled material with high pressure water streams.
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 precautions for fire-fighters	Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. 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.
Prevention of secondary hazards	Clean contaminated objects and areas thoroughly observing environmental regulations.

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.
---------------------------	--

8. Exposure controls/personal protection

Working area parameters, subject to mandatory control (MAC or TSEL)

Exposure Limits	This product, as supplied, contains materials that do not have reportable occupational exposure limits or are not subject to the reporting requirements of the local jurisdiction.
Biological occupational exposure limits	This product, as supplied, contains materials that do not have reportable biological exposure limits or are not subject to the reporting requirements of the local jurisdiction.

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

Appropriate respiratory protection should be selected and used according to the chemical nature, hazards and use of this product and safety requirements of the local jurisdiction. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.

9. Physical and chemical properties

Information on basic physical and chemical properties

Appearance	powder or cake, lyophilized
Physical state	Solid
Color	light yellow
Odor (includes odor threshold)	Slight

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
pH	7.4-7.9	
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	None known
Decomposition temperature	No data available	None known
Kinematic viscosity	No data available	None known
Dynamic viscosity	No data available	None known

Other information

10. Stability and reactivity

Reactivity	No information available.
Chemical stability	Stable under normal conditions.
Possibility of hazardous reactions	None under normal processing.
Conditions to avoid	None known based on information supplied.
Incompatible materials	None known based on information supplied.
Hazardous decomposition products	None known based on information supplied.

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 No information available.

Numerical measures of toxicity

The following ATE values have been calculated for the mixture
ATEmix (oral) 28,328.60 mg/kg

Component Information

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Sodium chloride 7647-14-5	= 3550 mg/kg (Rat)	> 10000 mg/kg (Rabbit)	> 42 mg/L (Rat) 1 h

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.

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.

Chemical name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Sodium chloride 7647-14-5	-	LC50: 5560 - 6080mg/L (96h, Lepomis macrochirus) LC50: =12946mg/L (96h, Lepomis macrochirus) LC50: 6020 - 7070mg/L (96h, Pimephales promelas) LC50: =7050mg/L (96h, Pimephales promelas) LC50: 6420 - 6700mg/L (96h, Pimephales promelas) LC50: 4747 - 7824mg/L (96h, Oncorhynchus mykiss)	-	EC50: =1000mg/L (48h, Daphnia magna) EC50: 340.7 - 469.2mg/L (48h, Daphnia magna)

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.

Contaminated packaging

Do not reuse empty containers.

14. Transport information**DOT**

Not regulated

TDG

Not regulated

MEX

Not regulated

ICAO (air)

Not regulated

IATA

Not regulated

IMDG

Not regulated

15. Regulatory information

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

International Inventories Contact supplier for inventory compliance status

US Federal Regulations

TSCA

All chemical components are listed on the TSCA Inventory.

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).

CAA (Clean Air Act)

This product does not contain any substances regulated as pollutants pursuant to Clean Air Act (CAA).

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
2-Propylpentanoic acid - 99-66-1	Developmental
Lithium carbonate - 554-13-2	Developmental
Streptomycin sulfate - 3810-74-0	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-oxo butyl]-2-deoxy- - 37517-28-5	Developmental
Diphenylhydantoin, sodium salt - 630-93-3	Carcinogen
Carbamazepine - 298-46-4	Developmental

Primidone - 125-33-7	Carcinogen
Tobramycin - 32986-56-4	Developmental
Gentamicin, sulfate (salt) - 1405-41-0	Developmental
Methotrexate - 59-05-2	Developmental
2-Butyl-3-benzofuryl 4-[2-(diethylamino)ethoxy]-3,5-diiodophenyl ketone hydrochloride - 19774-82-4	Developmental Female Reproductive Male Reproductive
Cyclosporin A - 59865-13-3	Carcinogen
Haloperidol - 52-86-8	Developmental Female Reproductive

U.S. State Right-to-Know Regulations

Chemical name	New Jersey	Massachusetts	Pennsylvania
2-Propylpentanoic acid 99-66-1	-	X	-
Lithium carbonate 554-13-2	X	X	-
Phenobarbital 50-06-6	-	X	-
Chloramphenicol 56-75-7	-	X	X
Diphenylhydantoin, sodium salt 630-93-3	-	-	X
Methotrexate 59-05-2	-	X	-
Digoxin 20830-75-5	X	X	X

U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable

16. Other information

NFPA Health hazards 0 Flammability 0 Instability 0 Special hazards -
HMIS Health hazards 0 Flammability 0 Physical hazards 0 Personal protection -
 Chronic Hazard Star Legend * = Chronic Health Hazard

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

ADN	Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways (Europe)
ADR	Agreement concerning the International Carriage of Dangerous Goods by Road (Europe)
ATE	Acute Toxicity Estimate
ASTM	American Society for the Testing of Materials
BEL	Biological exposure limits
bw	Body weight
Ceiling	Maximum limit value
CMR	Carcinogen, Mutagen or Reproductive Toxicant
DOT	Department of Transportation (United States)
EmS	Emergency Schedule
EPA	Environmental Protection Agency
GHS	Globally Harmonized System
HMIS	Hazardous Materials Identification System
IATA	International Air Transport Association
ICAO	International Civil Aviation Organization
IMDG	International Maritime Dangerous Goods

IMO	International Maritime Organization
ISO	International Organization for Standardization
LC50	Lethal Concentration to 50% of a test population
LD50	Lethal Dose to 50% of a test population (Median Lethal Dose)
MARPOL	International Convention for the Prevention of Pollution from Ships
NFPA	National Fire Protection Association
NIOSH	National Institute for Occupational Safety and Health
n.o.s.	Not Otherwise Specified
NOAEL	No Observed Adverse Effect Level
OECD	Organization for Economic Cooperation and Development
OEL	Occupational exposure limits
OSHA	Occupational Safety and Health Administration of the US Department of Labor
PBT	Persistent, Bioaccumulative and Toxic substance
PMT	Persistent, Mobile and Toxic
PPE	Personal protective equipment
RID	Agreement concerning the International Carriage of Dangerous Goods by Rail (Europe)
SARA	Superfund Amendments and Reauthorization Act
SDS	Safety Data Sheet
STEL	Short Term Exposure Limit
STOT RE	Specific target organ toxicity - Repeated exposure
STOT SE	Specific target organ toxicity - Single exposure
TDG	Transport of Dangerous Goods (Canada)
TSCA	Toxic Substances Control Act (United States)
TWA	Time-Weighted Average
UN	United Nations
VOC	Volatile organic compounds
vPvB	Very Persistent and Very Bioaccumulative
vPvM	Very Persistent and Very Mobile
Sk	Skin notation

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

Prepared By Bio-Rad Laboratories, Environmental Health and Safety.
Revision date 01-May-2025
Revision Note Reviewed existing information and made minor updates.
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