

SAFETY DATA SHEET

This safety data sheet complies with the requirements of: SS586: 2008 (2014)

Revision date 05-Dec-2024

Revision Number 0.1

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

Product identifier				
Product Name	Lyphochek Whole Blood Immunosuppressant Control			
Other means of identification				
Catalogue Number(s)	274, 275, 276, 277, 278, 279X			
Pure substance/mixture	Mixture			
Recommended use of the chemical	and restrictions on use			
Recommended use	In vitro diagnostic			
Uses advised against	No information available			
Details of the supplier of the safety	Details of the supplier of the safety data sheet			
Corporate Headquarters Bio-Rad Laboratories Inc. 1000 Alfred Nobel Drive Hercules, CA 94547 USA For further information, please contact	<u>Manufacturer</u> Bio-Rad Laboratories Inc. 9500 Jeronimo Road Irvine, California 92618 USA	Legal Entity / Contact Address Bio-Rad Laboratories (Singapore) PTE LTD 3A International Business Park #11-10/16 ICON@IBP Singapore 609935		
Technical Service	6424 0262 ctssingapore@bio-rad.com			
Emergency telephone number				

24 Hour Emergency Phone Number CHEMTREC Singapore: 65-31581349

SECTION 2: Hazards identification

GHS Classification

Not a hazardous substance or mixture according to the Globally Harmonised System (GHS): SS586: 2008 (2014)

Label elements

Not a hazardous substance or mixture according to the Globally Harmonised System (GHS): SS586: 2008 (2014)

Other hazards which do not result in classification

Contains human source material and / or potentially infectious components

SECTION 3: Composition/information on ingredients

Substance

Not applicable

<u>Mixture</u>

Chemical name	EC No (EU Index No)	CAS No.	Weight-%	
Sucrose	200-334-9	57-50-1	5 - 10	
Non-hazardous ingredients	Proprietary Balance			
SECTION 4: First aid me	asures			
Description of first aid measures	1			
General advice	No hazards which require	special first aid measures.		
Inhalation	Remove to fresh air.			
Eye contact	Call a doctor. Rinse immed minutes.	diately with plenty of water, also u	nder the eyelids, for at least 15	
Skin contact	Wash with soap and water			
Ingestion	Call a doctor.			
Most important symptoms and e	ffects, both acute and delaye	<u>d</u>		
Symptoms	No information available.	No information available.		
For emergency responders				
Self-protection of the first aider	aider No information available.			
Indication of any immediate medical attention and special treatment needed				
lote to doctors Treat symptomatically.				
SECTION 5: Firefighting	measures			
Suitable Extinguishing Media				
Suitable Extinguishing Media	Use extinguishing measure surrounding environment.	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.		
Unsuitable extinguishing media	No information available.			
Specific hazards arising from the chemical				
Specific hazards arising from the chemical	None known.			
Special protective actions for fire-fighters				

Special protective equipment and precautions for fire-fighters

Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

SECTION 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures			
Personal precautions	Ensure adequate ventilation.		
For emergency responders	Use personal protection recommended in Section 8.		
Environmental precautions			
Environmental precautions	See Section 12 for additional Ecological Information.		
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.		
Reference to other sections	See section 8 for more information. See section 13 for more information.		

SECTION 7: Handling and storage

Advice on safe handling	Ensure adequate ventilation.

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

Conditions for safe storage, including any incompatibilities

Storage Conditions

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

SECTION 8: Exposure controls/personal protection

Control parameters

Occupational exposure limits

Chemical name	Singapore	ACGIH TLV
Sucrose	PEL: 10 mg/m ³	TWA: 10 mg/m ³
57-50-1	_	-

Biological occupational exposure limits

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

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).		
Skin and body protection	Wear suitable protective clothing.		
Hand protection	Wear suitable gloves.		
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.		

Environmental exposure controls No information available.

SECTION 9: Physical and chemical properties

Information on basic physical and chemical properties

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

Property_	Values	Remarks • Method
pH	6.9-7.1	
Melting point / freezing point	No data available	None known
Initial boiling point and boiling rang	eNo 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	No data available	
limits		
Lower flammability or explosive	No data available	
limits		
Vapour pressure	No data available	None known
Relative 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	
Other information	No information available	

SECTION 10: Stability and reactivity

Reactivity

Reactivity

No information available.

Chemical stability

Stability	Stable under normal conditions.
Explosion data Sensitivity to mechanical impac Sensitivity to static discharge	t None. None.
Possibility of hazardous reactions	None under normal processing.
Conditions to avoid	
Conditions to avoid	None known based on information supplied.
Incompatible materials	
Incompatible materials	None known based on information supplied.
Hazardous decomposition products	<u>5 </u>

Hazardous decomposition products None known based on information supplied.

SECTION 11: Toxicological information

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.

Acute toxicity

Numerical measures of toxicity No information available

Component Information

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Sucrose	= 29700 mg/kg (Rat)		
Ethylenediaminetetraacetic acid	> 2000 mg/kg (Rat)		
Cyclosporin A	= 1480 mg/kg (Rat)		
Tacrolimus	= 134 mg/kg (Rat)		

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	Classification not possible.

SECTION 12: Ecological information

<u>Ecotoxicity</u>	
Ecotoxicity	The environmental impact of this product has not been fully investigated.
Persistence and degradability	
Persistence and degradability	No information available.
Bioaccumulative potential	
Bioaccumulation	No information available.
Mah 1144	
<u>Mobility</u>	
Mobility in soil	No information available.
PBT and vPvB assessment	No information available
Other adverse effects	
Other adverse effects	No information available

SECTION 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.	

SECTION 14: Transport information

ADR	Not regulated
IMDG Transport in bulk according to Annex II of MARPOL and the IBC Code	Not regulated No information available C

<u>IATA</u>

Not regulated

SECTION 15: Regulatory information

Safety, health and environmental regulations/legislation specific for the substance or mixture

Singapore

Environmental Public Health Act

Dispose of waste product or used containers according to local regulations.

Hazardous Waste (Control of Export, Import and Transit) Act

It is the responsibility of the waste generator to determine the toxicity and physical properties of the material generated to determine the proper waste identification and disposal methods in compliance with applicable regulations. Take note that wastes may be subject to export, import, or transit controls pursuant to the Basel convention and/or local regulations implementing the Basel convention.

Poison

None Listed Workplace Safety and Health Act

See section 8 for national exposure control parameters. Comply with the health and safety at work laws.

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

SECTION 16: Other information

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

Legend	Section 8: EXPOSURE CONTROLS/PERSONAL
TŴA	TWA (time-weighted average)
Ceiling	Maximum limit value

<u>PROTECTION</u> STEL Sk*

STEL (Short Term Exposure Limit) 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) 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) U.S. 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 I abel elements

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Revision Note	Reviewed existing information and made minor updates.

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Disclaimer

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End of Safety Data Sheet