

SAFETY DATA SHEET

According to WHS Regulations

Revision date 08-Mar-2021 Revision Number 1

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

Product identifier

Product Name Lyphochek Fertility Control, Level 3

Catalogue Number(s) 483

Other means of identification

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 manufacturer or importer

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

Hercules, CA 94547 USA Manufacturer

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

USA

Legal Entity / Contact Address

Bio-Rad Laboratories Pty Ltd

Level 5

446 Victoria Road, Gladesville NSW 2111

Australia

For further information, please contact

Technical Service +61 2 9914 2800 or 1800 224 354

sales.australia@bio-rad.com

Emergency telephone number

24 Hour Emergency Phone Number CHEMTREC Australia: 61-290372994

SECTION 2: Hazards identification

GHS Classification

Not classified

Label elements

Hazard statements

Not classified

Other hazards which do not result in classification

General Hazards Contains human source material and / or potentially infectious components

SECTION 3: Composition/information on ingredients

Substance

Not applicable

Mixture

Chemical name	CAS No	Weight-%
Testosterone	58-22-0	< 0.001
Progesterone	57-83-0	< 0.001
Follicle-stimulating hormone	9002-68-0	< 0.001
Estradiol-17b	50-28-2	< 0.001
Estra-1,3,5(10)-triene-3,16,17-triol, (16.alpha.,17.beta.)-	50-27-1	< 0.001
Digitoxin	71-63-6	< 0.001
1,3-Propanediol, 2-amino-2-(hydroxymethyl)-	77-86-1	< 0.001
Sodium phosphate dibasic	7558-79-4	< 0.001
Potassium chloride	7447-40-7	< 0.001
Non-hazardous ingredients	Proprietary	Balance

SECTION 4: First aid measures

Description of first aid measures

General advice No hazards which require special first aid measures.

Emergency telephone number Poisons Information Centre, Australia: 13 11 26

Poisons Information Centre, New Zealand: 0800 764 766

Inhalation Remove to fresh air.

Eye contact Contains human source material and / or potentially infectious components. Call a doctor.

Skin contact Wash skin with soap and water.

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

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 doctorsContains human source material and / or potentially infectious components.

SECTION 5: Firefighting measures

Suitable Extinguishing Media

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 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 See section 8 for more information.

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 Do not allow into any sewer, on the ground or into any body of water.

Clean contaminated surface thoroughly. Use:. Disinfectant. Methods for cleaning up

Precautions to prevent secondary hazards

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

SECTION 7: Handling and storage

Precautions for safe handling

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

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

Conditions for safe storage, including any incompatibilities

Storage Conditions Store according to product and label instructions.

Metals. Incompatible materials

SECTION 8: Exposure controls/personal protection

Control parameters

This product, as supplied, does not contain any hazardous materials with occupational **Exposure Limits**

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

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 protectionWear 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 light yellow Odour Slight.

Odour threshold No information available

<u>Property</u> <u>Values</u> <u>Remarks • Method</u>

pH 7.3-7.7

No data available None known Melting point / freezing point Boiling point / boiling range No data available None known Flash point No data available None known No data available **Evaporation rate** None known Flammability (solid, gas) 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 pressureNo data availableNone knownVapour densityNo data availableNone knownRelative densityNo data availableNone known

Water solubility
Soluble in water
No data available
No data available
No data available

Solubility(ies)No data availableNone knownPartition coefficientNo data availableNone knownAutoignition temperatureNo data availableNone knownDecomposition temperatureNo data availableNone knownKinematic viscosityNo data availableNone knownDynamic viscosityNo data availableNone known

Explosive properties

Oxidising properties

Not applicable
Not applicable

Other information

Molecular weight Not applicable VOC Content (%) Not applicable

SECTION 10: Stability and reactivity

Reactivity

Reactivity No information available.

Chemical stability

Stability Stable under normal conditions.

Explosion data

Sensitivity to mechanical impact None.

Sensitivity to static discharge None.

Possibility of hazardous reactions

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

Conditions to avoidNone known based on information supplied.

Incompatible materials

Incompatible materials Metals.

Hazardous decomposition products

Hazardous decomposition products None known based on information supplied.

SECTION 11: Toxicological information

Acute toxicity

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 No information available.

Numerical measures of toxicity - Product Information

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Estra-1,3,5(10)-triene-3,16,17-tri	> 2 g/kg (Rat)	-	-
ol, (16.alpha.,17.beta.)-			
Digitoxin	= 23750 μg/kg (Rat)	-	-
	= 23.75 mg/kg (Rat)		
1,3-Propanediol,	= 5900 mg/kg (Rat)	-	-

2-amino-2-(hydroxymethyl)-			
Sodium phosphate dibasic	= 17 g/kg(Rat)	-	-
Potassium chloride	= 2600 mg/kg (Rat)	-	-

See section 16 for terms and abbreviations

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

Skin corrosion/irritationBased 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 exposureBased on available data, the classification criteria are not met.

STOT - repeated exposureBased 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

Ecotoxicity

Ecotoxicity .

Unknown aquatic toxicity 0 % of the mixture consists of component(s) of unknown hazards to the aquatic

environment.

Chemical name	Algae/aquatic plants	Fish	Toxicity to	Crustacea
			microorganisms	
Potassium chloride	EC50: =2500mg/L (72h,	LC50: 750 - 1020mg/L	-	EC50: =825mg/L (48h,
	Desmodesmus	(96h, Pimephales		Daphnia magna)
	subspicatus)	promelas)		EC50: =83mg/L (48h,
		LC50: =1060mg/L (96h,		Daphnia magna)
		Lepomis macrochirus)		

Persistence and degradability

Persistence and degradability No information available.

Bioaccumulative potential

Bioaccumulation No information available.

Mobility

Mobility in soil No information available.

Mobility No information available.

Other adverse effects

No information available. Other adverse effects

SECTION 13: Disposal considerations

Waste treatment methods

Waste from residues/unused

products

Flush pipes with water frequently if discarding solutions containing Sodium azide into metal piping systems. 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

Not regulated ADG

Not regulated IATA IMDG Not regulated

Transport in bulk according to Annex II of MARPOL and the IBC Code

No information available

SECTION 15: Regulatory information

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

National regulations

Australia

See section 8 for national exposure control parameters

Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP)

No poisons schedule number allocated

International Inventories

Contact supplier for inventory compliance status

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

SECTION 16: Other information

Prepared By Bio-Rad Laboratories, Environmental Health and Safety

08-Mar-2021 Revision date

Revision Note

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 * Skin designation

C Carcinogen

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

Disclaimer

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End of Safety Data Sheet

^{***} Indicates this information has changed since the previous revision.