SAFETY DATA SHEET



Legal Entity / Contact Address

Bio-Rad Laboratories Inc.

9500 Jeronimo Road

USA

Irvine, California 92618

Revision date 08-Mar-2021 Revision Number 1

1. Identification

Product identifier

Product Name Lyphochek Fertility Control, Level 1

Other means of identification

Catalog Number(s) 481

Recommended use of the chemical and restrictions on use

Recommended use In vitro diagnostic

Details of the supplier of the safety data sheet

Corporate HeadquartersManufacturer AddressBio-Rad Laboratories Inc.Bio-Rad Laboratories Inc.1000 Alfred Nobel Drive9500 Jeronimo RoadHercules, CA 94547Irvine, California 92618

USA USA

Technical Service 1(800) 854-6737

gsd.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

Not a hazardous substance or mixture according to the Globally Harmonized System (GHS)

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 human source material and / or potentially infectious components.

3. Composition/information on ingredients

Substance

Not applicable.

<u>Mixture</u>

4. First-aid measures

Description of first aid measures

General advice No hazards which require special first aid measures.

Inhalation Remove to fresh air.

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

physician.

Skin contact Wash skin with soap and water.

Ingestion Call a physician. 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

5. Fire-fighting measures

surrounding environment.

Unsuitable extinguishing media No information available.

Specific hazards arising from the

chemical

None known.

Explosion data

Sensitivity to mechanical impact None. Sensitivity to static discharge None.

Special protective equipment for

fire-fighters

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

6. Accidental release measures

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

Personal precautions, protective equipment and emergency procedures

Personal precautions See section 8 for more 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.

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

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

exposure 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).

Hand protection Wear suitable gloves.

Skin and body protectionWear suitable protective clothing.

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 light yellow Odor Slight

Odor threshold No information available

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

pH 7.3-7.7

Melting point / freezing point No data available None known

Boiling point / boiling rangeNo data availableNone knownFlash pointNo data availableNone knownEvaporation rateNo data availableNone knownFlammability (solid, gas)No data availableNone knownFlammability Limit in AirNone known

Upper flammability or explosive No data available

limits

Lower flammability or explosive No data available

limits

Vapor pressureNo data availableNone knownVapor densityNo data availableNone knownRelative densityNo data availableNone known

Water solubility Soluble in water

Solubility in other solventsNo data availableNone knownPartition coefficientNo data availableNone knownAutoignition temperatureNo data availableNone knownDecomposition temperatureNo data availableNone known

Kinematic viscosity

No data available

None known

No data available

None known

None known

Other information

Explosive properties

Oxidizing properties

Not applicable
Not applicable
Not applicable
Not applicable
VOC Content (%)

Not applicable
Not applicable

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 avoidNone 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

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

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

ATEmix (oral) 11,472.20 mg/kg **ATEmix (dermal)** 38,279.05 mg/kg

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 sensitization 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 exposureBased on available data, the classification criteria are not met.

Aspiration hazard No information available.

Other adverse effects No information available.

Interactive effects No information available.

12. Ecological information

Ecotoxicity

Persistence and degradability No information available.

Bioaccumulation There is no data for this product.

Other adverse effects No information available.

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.

14. Transport information

DOTNot regulatedTDGNot regulatedMEXNot regulatedIATANot regulatedIMDGNot 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. Under the amended regulations at 40 CFR 370, EPCRA 311/312 Tier II reporting for the 2017 calendar year will need to be consistent with updated hazard 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
Estradiol-17b - 50-28-2	Carcinogen
Progesterone - 57-83-0	Carcinogen
Testosterone - 58-22-0	Carcinogen
	Female Reproductive
	Male Reproductive
Follicle-stimulating hormone - 9002-68-0	Developmental

U.S. State Right-to-Know Regulations

US State Regulations This product does not contain any substances regulated by state right-to-know regulations

US State Regulations

U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable

16. Other information

Instability 0 NFPA Health hazards 0 Flammability 0 Physical and chemical

properties -

HMIS Health hazards 0 Flammability 0 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)

Maximum limit value Ceiling 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) 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

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)

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

RTECS (Registry of Toxic Effects of Chemical Substances)

World Health Organization

Prepared By Bio-Rad Laboratories, Environmental Health and Safety

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*** Indicates this information has changed since the previous revision. **Revision Note**

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