



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 1

Catalogue Number(s) 481

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
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

Emergency telephone number No information available

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 doctors | Contains human source material and / or potentially infectious components. |
|------------------------|--|

SECTION 5: Firefighting measures**Suitable Extinguishing Media**

| | |
|-------------------------------------|---|
| Suitable Extinguishing Media | 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 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.

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

Precautions to prevent secondary hazards

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

SECTION 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.

Incompatible materials Metals.

SECTION 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.

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 | light yellow |
| Odour | Slight. |
| Odour threshold | No information available |

| Property | Values | Remarks • Method |
|---|-------------------|-------------------------|
| pH | 7.3-7.7 | |
| Melting point / freezing point | No data available | None known |
| Boiling point / boiling range | No data available | None known |
| Flash point | No data available | None known |
| Evaporation rate | No data available | None known |
| Flammability (solid, gas) | 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 | |
| Vapour pressure | No data available | None known |
| 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 | | |
| 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 avoid None 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

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

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

| | | | |
|--|-----------------------|---|---|
| | = 23.75 mg/kg (Rat) | | |
| 1,3-Propanediol, 2-amino-2-(hydroxymethyl)- | = 5900 mg/kg (Rat) | - | - |
| 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/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 | 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 microorganisms | Crustacea |
|--------------------|--|---|----------------------------|---|
| Potassium chloride | EC50: =2500mg/L (72h, <i>Desmodesmus subspicatus</i>) | LC50: 750 - 1020mg/L (96h, <i>Pimephales promelas</i>) LC50: =1060mg/L (96h, <i>Lepomis macrochirus</i>) | - | EC50: =825mg/L (48h, <i>Daphnia magna</i>) EC50: =83mg/L (48h, <i>Daphnia magna</i>) |

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

Other adverse effects No information available.

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

ADG Not regulated

IATA Not regulated

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

Revision date 08-Mar-2021

Revision Note

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

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) (AELG(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 (IUCID)
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