

Safety Data Sheet

acc. to OSHA HCS

Printing date 05/26/2015

Reviewed on 05/26/2015

1 Identification

- **Product identifier**
- **Trade name:** *Lyphochek® Therapeutic Drug Monitoring Control (TDM)*
- **Catalog or product number:** 450, 451, 452, 453, 450X
- **Relevant identified uses of the substance or mixture and uses advised against**
- **Sector of Use** SU20 Health services
- **Application of the substance / the mixture** *In-vitro laboratory reagent or component*
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Bio-Rad Laboratories, Diagnostic Group
9500 Jeronimo Road
Irvine, California 92618-2017 1(949) 598-1200
- **Information department:** *Technical services, customer support*
- **Emergency telephone number:**
1(800) 424-9300 *Use only in the event of a CHEMICAL EMERGENCY involving a SPILL, LEAK, FIRE, EXPLOSION, or ACCIDENT.*

2 Hazard(s) identification

- **Classification of the substance or mixture**
Skin Irrit. 2 H315 Causes skin irritation.
Eye Irrit. 2A H319 Causes serious eye irritation.
- **Label elements**
- **GHS label elements** *The product is classified and labeled according to the Globally Harmonized System (GHS).*
- **Hazard pictograms**



GHS07

- **Signal word** *Warning*
- **Hazard statements**
H315 Causes skin irritation.
H319 Causes serious eye irritation.
- **Precautionary statements**
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P305+P351+P338 If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P363 Wash contaminated clothing before reuse.
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P337+P313 If eye irritation persists: Get medical advice/attention.
P302+P352 If on skin: Wash with plenty of water.
- **Emergency overview:**
- **Routes of exposure:**
Ingestion
Inhalation
Skin

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- **Classification system**
- **NFPA ratings (scale 0-4)**
Health = 1
Fire = 0
Reactivity = 0
- **Special Hazards** Contains human sourced and/or potentially infectious components.
- **Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

3 Composition/information on ingredients

- **Chemical characterization: Mixtures**
- **Description:** Mixture of the substances listed below with non-hazardous additions.

· **Listing of dangerous and non-hazardous components:**

EINECS: 268-338-3	Human Source Material	50-100%
CAS: 7647-14-5 EINECS: 231-598-3	sodium chloride	10-20%
CAS: 56-75-7 EINECS: 200-287-4	chloramphenicol	0.01-0.1%

- **Additional information**
Contains human sourced and/or potentially infectious components.
Contains added constituents of animal origin.

4 First-aid measures

- **Description of first aid measures**
- **After inhalation** Supply fresh air; consult doctor in case of complaints.
- **After skin contact** Immediately wash with water and soap and rinse thoroughly.
- **After eye contact** Rinse opened eye for several minutes under running water. Then consult a doctor.
- **After swallowing** Rinse mouth with water. Seek medical attention and appropriate follow-up.
- **Information for doctor**
- **Most important symptoms and effects, both acute and delayed**
Skin irritation
Eye irritation
- **Indication of any immediate medical attention and special treatment needed** No further relevant information available.

5 Fire-fighting measures

- **Extinguishing media**
- **Suitable extinguishing agents**
CO2, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **Special hazards arising from the substance or mixture** No further relevant information available.

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- **Advice for firefighters**
- **Protective equipment:** No special measures required.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** Handle as potentially infectious.
- **Environmental precautions:**
Keep contaminated washing water and dispose of appropriately.
Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**
Absorb liquid components with liquid-binding material.
Pick up mechanically.
Clean the affected area carefully; suitable cleaners are:
Disinfectant
- **Reference to other sections** See Section 13 for disposal information.

7 Handling and storage

- **Handling**
- **Precautions for safe handling** No special precautions are necessary if used correctly.
- **Information about protection against explosions and fires:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
- **Storage**
- **Requirements to be met by storerooms and receptacles:** According to product specification
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:**
Refer to package insert for additional information regarding storage conditions.
- **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see item 7.

· **Control parameters**

- **Components with limit values that require monitoring at the workplace:**

56-75-7 chloramphenicol

WEEL (United States)	0.5 mg/m ³
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- **Additional information:** The lists that were valid during the creation were used as basis.

· **Exposure controls**

· **Personal protective equipment**

· **General protective and hygienic measures**

Follow the usual biosafety practices for handling infectious materials.
The usual precautionary measures for handling chemicals should be followed.

- **Breathing equipment:** Not required.

- **Protection of hands:** Protective gloves.

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Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

Synthetic gloves

Penetration time of glove material

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

Eye protection: Safety glasses

Body protection: Protective work clothing.

9 Physical and chemical properties

Information on basic physical and chemical properties

General Information

Appearance:

Form:	Solid
Color:	Light yellow
Odor:	Light

pH-value at 20 °C: 7.4-7.9

Change in condition

Melting point/Melting range: undetermined
Boiling point/Boiling range: undetermined

Flash point: Not applicable

Flammability (solid, gaseous) Not determined.

Danger of explosion: Product does not present an explosion hazard.

Density: Not determined

Solubility in / Miscibility with Water:

Soluble

Solvent content:

Organic solvents: 0.0 %

Solids content: 100 %

Other information No further relevant information available.

10 Stability and reactivity

Reactivity

Chemical stability

Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.

Possibility of hazardous reactions No dangerous reactions known

Conditions to avoid No further relevant information available.

Incompatible materials: No further relevant information available.

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· **Hazardous decomposition products:** No dangerous decomposition products known

11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**
- **Primary irritant effect:**
- **on the skin:** Irritant to skin and mucous membranes.
- **on the eye:** Irritant effect.
- **Sensitization:** No sensitizing effects known.
- **Additional toxicological information:**
- **Carcinogenic categories**

· **IARC (International Agency for Research on Cancer)**

103-90-2	paracetamol	3
50-06-6	phenobarbital	2B
58-55-9	theophylline	3
56-75-7	chloramphenicol	2A
58-08-2	caffeine	3
59-05-2	methotrexate	3

· **NTP (National Toxicology Program)**

56-75-7	chloramphenicol	R
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· **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behavior in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:**
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water.
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

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13 Disposal considerations

- **Waste treatment methods**
- **Recommendation** Dispose of waste in accordance to applicable national, regional, or local regulations.
- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.
- **Recommended cleansing agent:** Water, if necessary with cleansing agents.

14 Transport information

- | | |
|--|-----------------|
| · UN-Number
· ADR, ADN, IMDG, IATA | Void |
| · UN proper shipping name
· ADR, ADN, IMDG, IATA | Void |
| · Transport hazard class(es)
· ADR, ADN, IMDG, IATA
· Class | Void |
| · Packing group
· ADR, IMDG, IATA | Void |
| · Environmental hazards:
· Marine pollutant: | No |
| · Special precautions for user | Not applicable. |
| · Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code | Not applicable. |

15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **SARA (Superfund Amendments and Reauthorization Act of 1986 - USA)**

· **Section 302/304 (40CFR355.30 / 40CFR355.40):**

20830-75-5	digoxin
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· **Section 313 (40CFR372.65):**

554-13-2	lithium carbonate
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· **TSCA (Toxic Substances Control Act):**

7647-14-5	sodium chloride
69-72-7	Salicylic acid
7447-40-7	potassium chloride
103-90-2	paracetamol
554-13-2	lithium carbonate
3810-74-0	streptomycin sulphate

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58-55-9	theophylline
56-75-7	chloramphenicol
630-93-3	Phenytoin Sodium
58-08-2	caffeine
614-39-1	Procainamide hydrochloride
59-05-2	methotrexate
549-18-8	amitriptyline hydrochloride
50-23-7	hydrocortisone
20830-75-5	digoxin

· California Proposition 65:

· Chemicals known to cause cancer:

50-06-6	phenobarbital
56-75-7	chloramphenicol
630-93-3	Phenytoin Sodium

· Developmental Toxicity

99-66-1	2-propylvaleric acid
554-13-2	lithium carbonate
3810-74-0	streptomycin sulphate
298-46-4	Carbamazepin
32986-56-4	tobramycin
1405-41-0	Gentamicin Sulfate
59-05-2	methotrexate
52-86-8	haloperidol

· Carcinogenic categories

· EPA (Environmental Protection Agency)

None of the ingredients is listed.

· TLV (Threshold Limit Value established by ACGIH)

None of the ingredients is listed.

· MAK (German Maximum Workplace Concentration)

None of the ingredients is listed.

· NIOSH-Ca (National Institute for Occupational Safety and Health)

None of the ingredients is listed.

· National regulations

- Water hazard class:** Water hazard class 1 (Self-assessment): slightly hazardous for water.
- Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- Department issuing SDS:** Environmental Health and Safety.

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· Contact:

Life Science Group, Environmental Health and Safety, 2000 Alfred Nobel Drive, Hercules, California, 94547: 1(510) 741-1000

Diagnostic Group, Environmental Health and Safety, 4000 Alfred Nobel Drive, Hercules, California, 94547: 1(510) 724-7000

· Date of preparation / last revision 05/26/2015 / -**· Abbreviations and acronyms:**

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

ACGIH: American Conference of Governmental Industrial Hygienists

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

NFPA: National Fire Protection Association (USA)

Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2

Eye Irrit. 2A: Serious eye damage/eye irritation, Hazard Category 2A

· * Data compared to the previous version altered.

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