

Lymphoprep™

Safety Data Sheet

according to Federal Register / Vol. 89, No. 98 / Monday, May 20, 2024 / Rules and Regulations

Date of issue: 09/23/2024

Revision date: -

Version/Replaced version: 1.0/-

SECTION 1: Identification

1.1. Product identifier

Product form : Mixture
Product name : Lymphoprep™

1.2. Relevant identified uses of the substance or mixture and uses advised against

Recommended use : Density gradient media
Restrictions on use : Not intended for use as infusion solution.

1.3. Details of the supplier of the safety data sheet

Manufacturer / Supplier

Serumwerk Bernburg AG
Hallesche Landstrasse 105 b
06406 Bernburg - Germany
T + 49 3471 860 4939

1.4. Emergency telephone number

Country	Organisation/Company	Address	Emergency number
Germany	Giftinformationszentrum-Nord Zentrum Pharmakologie und Toxikologie der Universität Göttingen	Robert-Koch Strasse 40 D-37075 Göttingen	+49 551 19240 (German/English)

SECTION 2: Hazard identification

2.1. Classification of the substance or mixture

GHS-US classification in accordance with paragraph (d) of § 1910.1200

Not classified

2.2. Label elements

GHS-US labelling in accordance with paragraph (f) of § 1910.1200

No labelling applicable

2.3. Other hazards

No additional information available

2.4. Unknown acute toxicity (GHS-US)

Not applicable

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

This product does not contain hazardous ingredients at levels requiring disclosure by the OSHA Hazard Communication Standard (29 CFR 1910.1200).

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general : Get medical advice/attention if you feel unwell. If possible, show him this sheet. Failing this, show him the packaging or label. Never give anything by mouth to an unconscious person. Place the affected person in the recovery position.

First-aid measures after inhalation : Remove victim to fresh air and keep at rest in a position comfortable for breathing.

First-aid measures after skin contact : Take off contaminated clothing. Wash with plenty of soap and water.

First-aid measures after eye contact : If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

First-aid measures after ingestion : Rinse mouth. Drink water as a precaution. Do NOT induce vomiting.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/injuries : Not expected to present a significant hazard under anticipated conditions of normal use.

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Fire-fighting measures

5.1. Extinguishing media

Suitable extinguishing media : Adapt extinguishing agents to the environment. Carbon dioxide. Dry extinguishing powder. Water spray. For a significant fire: Alcohol resistant foam.

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Unsuitable extinguishing media : Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire : Toxic gases may be formed. Carbon dioxide. Carbon monoxide. Nitrogen oxides (NOx).

5.3. Advice for firefighters

Firefighting instructions : Use water spray or fog for cooling exposed containers. Prevent fire-fighting water from entering environment.

Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : Provide adequate ventilation. Avoid contact with skin and eyes.

Emergency procedures : Evacuate the danger area

Protective equipment : Use personal protective equipment as required. In case of inadequate ventilation wear respiratory protection. For further information refer to heading 8: "Exposure controls/personal protection".

6.2. Methods and materials for containment and cleaning up

Methods for cleaning up : Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible.

For containment : Keep in suitable, closed containers for disposal.

Other information : Dispose of in accordance with relevant local regulations.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Ensure good ventilation of the work station. Avoid contact with skin and eyes. Wear personal protective equipment.

Hygiene measures : Handle in accordance with good industrial hygiene and safety procedures. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. When using do not eat, drink or smoke.

7.2. Conditions for safe storage, including any incompatibilities

Technical measures : Take all necessary measures to avoid accidental discharge of products into drains and waterways due to the rupture of containers or transfer systems.

Storage conditions : Store in original container. Store in a well-ventilated place. Protect from sunlight.

Prohibitions on mixed storage : Keep away from food, drink and animal feedingstuffs.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Appropriate engineering controls

Appropriate engineering controls : Ensure good ventilation of the work station.

8.3. Individual protection measures, such as personal protective equipment

Hand protection : Wear suitable gloves. Nitrile rubber, ≥ 0.35 mm. The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

Eye protection : Chemical goggles or safety glasses.

Skin and body protection : Wear suitable protective clothing.

Respiratory protection : Where exposure through inhalation may occur from use, respiratory protection equipment is recommended. Breathing apparatus with filter A.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Liquid. Paste.

Color : Colorless, clear

Odor (includes odor threshold) : No data available

Melting point/freezing point : No data available

Boiling point (or initial boiling point or boiling range) : No data available

Flammability : No data available

Lower and upper explosion limit/flammability limit : No data available

Flash point : No data available

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Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
pH	: 6.3 – 7.3
Kinematic viscosity	: No data available
Solubility	: Water: soluble
Partition coefficient n-octanol/water (log value)	: Not applicable
Vapor pressure (includes evaporation rate)	: No data available
Density and/or relative density	: 1.08 g/cm ³ (20 °C)
Relative vapor density	: No data available
Particle characteristics	: Not applicable

SECTION 10: Stability and reactivity

10.1. Reactivity

To our knowledge, the product does not present any particular risk, under normal conditions of use.

10.2. Chemical stability

Stable at ambient temperature and under normal conditions of use and storage.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

High temperature. Direct sunlight. Frost.

10.5. Incompatible materials

Strong oxidizing agents. Strong bases. Strong acids.

10.6. Hazardous decomposition products

In case of fire: Toxic gases may be formed. Carbon dioxide. Carbon monoxide. Nitrogen oxides (NOx).

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity	: Not classified
Skin corrosion/irritation	: Not classified
Serious eye damage/irritation	: Not classified
Respiratory or skin sensitization	: Not classified
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified
Reproductive toxicity	: Not classified
Specific target organ toxicity (single exposure)	: Not classified
Specific target organ toxicity (repeated exposure)	: Not classified
Aspiration hazard	: Not classified
Symptoms/injuries after inhalation	: No known effects from this product.
Symptoms/injuries after ingestion	: No known effects from this product.
Symptoms/injuries after skin contact	: No known effects from this product.
Symptoms/injuries after eye contact	: No known effects from this product.

SECTION 12: Ecological information

12.1. Ecotoxicity

Ecology - general	: To our knowledge, the product does not present any particular risk, under normal conditions of use.
Acute aquatic toxicity	: Not classified
Chronic aquatic toxicity	: Not classified

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Other adverse effects

Effect on global warming	: No known effects from this product.
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SECTION 13: Disposal considerations

13.1. Waste treatment methods

Regional legislation (waste)	: Dispose in a safe manner in accordance with local/national regulations.
Waste disposal recommendations	: Empty the packaging completely prior to disposal. When totally empty, containers are recyclable like any other packing.

SECTION 14: Transport information

In accordance with DOT / ADR / IMDG / IATA

14.1. UN number

UN-No. (DOT)	: Not regulated for transport
UN-No. (ADR)	: Not regulated for transport
UN-No. (IMDG)	: Not regulated for transport
UN-No. (IATA)	: Not regulated for transport

14.2. UN proper shipping name

Proper Shipping Name (DOT)	: No additional information available
Proper Shipping Name (ADR)	: No additional information available
Proper Shipping Name (IMDG)	: No additional information available
Proper Shipping Name (IATA)	: No additional information available

14.3. Transport hazard class(es)

DOT

Transport hazard class(es) (DOT)	: No additional information available
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ADR

Transport hazard class(es) (ADR)	: No additional information available
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IMDG

Transport hazard class(es) (IMDG)	: No additional information available
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IATA

Transport hazard class(es) (IATA)	: No additional information available
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14.4. Packing group

Packing group (DOT)	: No additional information available
Packing group (ADR)	: No additional information available
Packing group (IMDG)	: No additional information available
Packing group (IATA)	: No additional information available

14.5. Environmental hazards

Dangerous for the environment	: No
Marine pollutant	: No
Other information	: No supplementary information available

14.6. Special precautions

DOT

Not applicable

ADR

Not applicable

IMDG

Not applicable

IATA

Not applicable

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

SECTION 15: Regulatory information

15.1. US Federal regulations

All substances in this mixture are listed on the United States TSCA (Toxic Substances Control Act) inventory with the exception of 3,5-diacetamido-2,4,6-triodobenzoic acid (CAS 117-96-4).

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Active Status: Active

15.2. International regulations

Canada

All substances in this mixture are listed on Canadian DSL (Domestic Substances List).

EU-Regulations

All substances in this mixture are listed on the EEC inventory EINECS (European Inventory of Existing Commercial Chemical Substances).

15.3. US State regulations

California Proposition 65

This product does not contain any substance(s) known to the state of California to cause cancer.

This product does not contain any substance(s) known to the state of California to cause developmental toxicity.

This product does not contain any substance(s) known to the state of California to cause reproductive toxicity.

SECTION 16: Other information, including date of preparation or last revision

Date of Preparation : 09/23/2024

Abbreviations and acronyms:

ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
DOT	Department of Transport, U.S. Department of Transportation Ground (49 CFR)
EC50	The effective concentration of substance that causes 50% of the maximum response (Median Effective Concentration)
IATA	International Air Transport Association
IMDG	"International Maritime Dangerous Goods Code" for the transport of dangerous goods by sea
LC50	Lethal Concentration to 50 % of a test population (Median Lethal Concentration)
LD50	Lethal Dose to 50% of a test population (Median Lethal Dose)
NOEC/L	No Observed Effect Concentration/Level
OECD	Organisation for Economic Cooperation and Development
SDS	Safety Data Sheet

SDS US (GHS HazCom 2024)

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.