

Lymphoprep™

Safety Data Sheet

according to Regulation (EU) 2020/878

Date of issue: 15.11.2021

Revision date: -

Version/Replaced version: 1.0/-

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

1.1. Product identifier

Product form : Mixture
Product name : Lymphoprep™
UFI : -

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

1.2.1. Relevant identified uses

Use of the substance/mixture : Density gradient media

1.2.2. Uses advised against

Not intended for use as infusion solution

1.3. Details of the supplier of the safety data sheet

Supplier / Manufacturer

Serumwerk Bernburg AG
Hallesche Landstrasse 105 b
06406 Bernburg - Germany
T + 49 3471 860 0

1.4. Emergency telephone number

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

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Not classified

Adverse physicochemical, human health and environmental effects

To our knowledge, this product does not present any particular risk, provided it is handled in accordance with good occupational hygiene and safety practice.

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

No labelling applicable

2.3. Other hazards

No additional information available

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

This mixture does not contain any substances to be mentioned according to the criteria of section 3.2 of REACH Annex II.

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. Place the affected person in the recovery position. Never give anything by mouth to an unconscious person.

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 plenty of water as a precaution. Do NOT induce vomiting.

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

Symptoms/effects : 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.

Lymphoprep™

Safety Data Sheet

according to Regulation (EU) 2020/878

SECTION 5: Firefighting 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.
- 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.

6.1.1. For non-emergency personnel

- Emergency procedures : Evacuate unnecessary personnel.

6.1.2. For emergency responders

- Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection"

6.2. Environmental precautions

- Prevent entry to sewers and public waters.

6.3. Methods and material 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. Keep in suitable, closed containers for disposal. Dispose of in accordance with relevant local regulations.

6.4. Reference to other sections

- Exposure controls and personal protection, see section 8. Concerning disposal elimination after cleaning, see section 13.

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. When using do not eat, drink or smoke. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Take off contaminated clothing and wash it before reuse.

7.2. Conditions for safe storage, including any incompatibilities

- 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.

7.3. Specific end use(s)

- No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

- No additional information available

8.2. Exposure controls

Appropriate engineering controls:

- Ensure good ventilation of the work station.

Hand protection:

- Wear suitable gloves (EN 374). 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 (EN 166).

Skin and body protection:

Lymphoprep™

Safety Data Sheet

according to Regulation (EU) 2020/878

Wear suitable protective clothing.

Respiratory protection:

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

Environmental exposure controls:

Avoid release to the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Colour	: Colorless, clear
Odour	: No data available
Melting point/freezing point	: No data available
Boiling point or initial boiling point and boiling range	: No data available
Flammability	: No data available
Lower and upper explosion limit	: No data available
Flash point	: No data available
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
Vapour pressure	: No data available
Density and/or relative density	: 1.08 g/cm ³ at 20 °C
Relative vapour density	: No data available
Particle characteristics	: Not applicable

9.2. Other information

9.2.1. Information with regard to physical hazard classes

Explosive properties	: No explosive properties
Oxidising properties	: No oxidising properties

9.2.2. Other safety characteristics

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No dangerous reactions known under normal conditions of use.

10.2. Chemical stability

Stable under use and storage conditions as recommended in section 7.

10.3. Possibility of hazardous reactions

None under normal 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

No hazardous decomposition products known. In case of fire: Toxic gases may be formed. Carbon dioxide. Carbon monoxide. Nitrogen oxides (NO_x).

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity	: Not classified
	Based on available data, the classification criteria are not met
Skin corrosion/irritation	: Not classified
	Based on available data, the classification criteria are not met

Lymphoprep™

Safety Data Sheet

according to Regulation (EU) 2020/878

Serious eye damage/irritation	: Not classified Based on available data, the classification criteria are not met
Respiratory or skin sensitisation	: Not classified Based on available data, the classification criteria are not met
Germ cell mutagenicity	: Not classified Based on available data, the classification criteria are not met
Carcinogenicity	: Not classified Based on available data, the classification criteria are not met
Reproductive toxicity	: Not classified Based on available data, the classification criteria are not met
Specific target organ toxicity (single exposure)	: Not classified Based on available data, the classification criteria are not met
Specific target organ toxicity (repeated exposure)	: Not classified Based on available data, the classification criteria are not met
Aspiration hazard	: Not classified Based on available data, the classification criteria are not met

11.2. Information on other hazards

Potential adverse human health effects and symptoms	: Based on available data, the classification criteria are not met
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SECTION 12: Ecological information

12.1. Toxicity

Ecology - general	: The product is not considered harmful to aquatic organisms nor to cause long-term adverse effects in the environment.
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. Results of PBT and vPvB assessment

The product does not meet the PBT- or vPvB criteria of REACH regulation, annex XIII.

12.6. Endocrine disrupting properties

No additional information available

12.7. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Regional legislation (waste)	: Dispose in a safe manner in accordance with local/national regulations.
Waste code	: The waste code number according to the Ordinance on the European Waste Catalogue depends on the waste producer and can therefore vary for any given product. The waste code number is therefore to be gleaned separately from each waste producer.

SECTION 14: Transport information

In accordance with ADR / IMDG / IATA

14.1. UN number or ID number

UN-No. (ADR)	: Not applicable
UN-No. (IMDG)	: Not applicable
UN-No. (IATA)	: Not applicable

14.2. UN proper shipping name

Proper Shipping Name (ADR)	: Not applicable
Proper Shipping Name (IMDG)	: Not applicable
Proper Shipping Name (IATA)	: Not applicable

14.3. Transport hazard class(es)

ADR

Lymphoprep™

Safety Data Sheet

according to Regulation (EU) 2020/878

Transport hazard class(es) (ADR) : Not applicable

IMDG

Transport hazard class(es) (IMDG) : Not applicable

IATA

Transport hazard class(es) (IATA) : Not applicable

14.4. Packing group

Packing group (ADR) : Not applicable

Packing group (IMDG) : Not applicable

Packing group (IATA) : Not applicable

14.5. Environmental hazards

Dangerous for the environment : No

Marine pollutant : No

Other information : No supplementary information available

14.6. Special precautions for user

- Overland transport

Not applicable

- Transport by sea

Not applicable

- Air transport

Not applicable

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

Contains no substance on the REACH candidate list

Contains no REACH Annex XIV substances

Contains no substance subject to Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals.

Contains no substance subject to Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No chemical safety assessment has been carried out.

SECTION 16: Other information

Data sources : REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Changes compared to the previous version : -

Abbreviations and acronyms:

ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
DMEL	Derived Minimal Effect Level
DNEL	Derived No-Effect Level
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)
LOAEL	Lowest Observed Adverse Effect Level

Lymphoprep™

Safety Data Sheet

according to Regulation (EU) 2020/878

NOAEC/L	No Observed Adverse Effect Concentration/Level
NOEC/L	No Observed Effect Concentration/Level
OECD	Organisation for Economic Cooperation and Development
PBT	Persistent, Bioaccumulative and Toxic substance
PNEC	Predicted No-Effect Concentration
REACH	Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals
SDS	Safety Data Sheet
STP	Sewage Treatment Plant
UFI	Unique Formula Identifier
vPvB	Very Persistent and Very Bioaccumulative

SDS EU (REACH Annex II)

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.