



SAFETY DATA SHEET

This safety data sheet complies with the requirements of:
SS586: 2008 (2014)

Revision date 13-Apr-2021

Revision Number 1

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

Product identifier

Product Name Lyphochek Diabetes Control

Other means of identification

Catalogue Number(s) 740, 740X

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 the supplier of the safety data sheet

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Hercules, CA 94547
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Manufacturer

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SECTION 2: Hazards identification

GHS Classification

Not a hazardous substance or mixture according to the Globally Harmonised System (GHS): SS586: 2008 (2014)

Label elements

Not a hazardous substance or mixture according to the Globally Harmonised System (GHS): SS586: 2008 (2014)

Other hazards which do not result in classification

SECTION 3: Composition/information on ingredients

Substance

Not applicable

Mixture

The product contains no substances which at their given concentration, are considered to be hazardous to health

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. |
| 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. |
|-----------------|---------------------------|

For emergency responders

| | |
|---|---------------------------|
| Self-protection of the first aider | 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 Ensure adequate ventilation.

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.

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

Reference to other sections See section 8 for more information. See section 13 for more information.

SECTION 7: Handling and storage**Precautions for safe handling**

Advice on safe handling Ensure adequate ventilation.

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.

SECTION 8: Exposure controls/personal protection**Control parameters**

Occupational 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 | red |
| Odour | Slight. |
| Odour threshold | No information available |

| <u>Property</u> | <u>Values</u> | <u>Remarks • Method</u> |
|--|--------------------------|-------------------------|
| pH | 7.95-8.05 | |
| 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 | |
| <u>Other information</u> | No information available | |

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 None under normal processing.

Conditions to avoid

Conditions to avoid None known based on information supplied.

Incompatible materials

Incompatible materials None known based on information supplied.

Hazardous decomposition products

Hazardous decomposition products None known based on information supplied.

SECTION 11: Toxicological information**Information on likely routes of exposure****Product Information**

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| | |
|---------------------|---|
| 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**

| Chemical name | Oral LD50 | Dermal LD50 | Inhalation LC50 |
|---------------|---|-------------------------|-------------------------|
| Trade secret | > 7500 mg/kg (Rat) | | |
| Trade secret | > 5 g/kg (Rat) | | |
| Trade secret | = 7.49 mg/kg (Rat) = 5 mg/kg (Rat) | = 22.3 mg/kg (Rabbit) | = 0.16 mg/L (Rat) 1 h |

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 Contains 0 % of components with unknown hazards to the aquatic environment

Persistence and degradability

Persistence and degradability No information available.

Bioaccumulative potential

Bioaccumulation No information available.

Mobility

Mobility in soil No information available.

PBT and vPvB assessment No information available

Other adverse effects

Other adverse effects No information available

SECTION 13: Disposal considerations

Waste treatment methods

Waste from residues/unused products 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

ADR Not regulated

IMDG Not regulated
Transport in bulk according to Annex II of MARPOL and the IBC Code No information available

IATA Not regulated

SECTION 15: Regulatory information

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

Singapore**Environmental Public Health Act**

Dispose of waste product or used containers according to local regulations.

Hazardous Waste (Control of Export, Import and Transit) Act

It is the responsibility of the waste generator to determine the toxicity and physical properties of the material generated to determine the proper waste identification and disposal methods in compliance with applicable regulations. Take note that wastes may be subject to export, import, or transit controls pursuant to the Basel convention and/or local regulations implementing the Basel convention.

Workplace Safety and Health Act

Comply with the health and safety at work laws.

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

International Inventories

Contact supplier for inventory compliance status

SECTION 16: Other information**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 |

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
 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

Label elements

Issuing Date Bio-Rad Laboratories, Environmental Health and Safety

Revision date 13-Apr-2021**Revision Note** *** Indicates this information has changed since the previous revision.**This safety data sheet complies with the requirements of: SS586: 2008 (2014)****Disclaimer**

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End of Safety Data Sheet