

Safety Data Sheet

According to Regulation (EU) No. 1907/2006 (REACH)

Product Name: Dialys-EO

Version: 03

Date: September 19, 2024



Section 1. Identification of the substance/mixture and of the company/undertaking

1.1. Product Identifier

Product Name: Dialys-EO

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

Relevant identified use

Laboratory reagent for in-vitro diagnostics in human samples

Uses advised against

No further relevant information available.

1.3. Details of the supplier of the safety data sheet

Dialab Produktion und Vertrieb von chemisch-technischen Produkten und Laborinstrumenten Gesellschaft m.b.H
Hondastrasse, Objekt M55, IZ-NOE Sued, 2351 Wr. Neudorf, Austria

Phone / e-mail: +43 2236 660 910 0 / office@dialab.at

Responsible person:

safety@dialab.at

1.4. Emergency telephone number

+43 1 406 43 43 (Gesundheit Österreich GmbH, 24 h)

Section 2. Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) 1272/2008 (CLP):

Aquatic Chronic 3 H412 Harmful to aquatic life with long lasting effects.

2.2. Label elements

Regulation (EC) 1272/2008 (CLP):

The product is classified and labelled according to the CLP regulation.

Pictogram(s) and signal words:

Hazard pictograms: Not classified as hazardous

Signal word: Not classified as hazardous

Precautionary statements

P273 Avoid release to the environment.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazard statements:

H412 Harmful to aquatic life with long lasting effects.

2.3. Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable

vPvB: Not applicable.

Determination of endocrine-disrupting properties

CAS: 9002-93-1 Polyethylene glycol octylphenol ether: List I

Section 3. Composition / information on ingredients

3.1. Substances

This product is a mixture.

Safety Data Sheet

According to Regulation (EU) No. 1907/2006 (REACH)

Product Name: Dialys-EO

Version: 03




Date: September 19, 2024

3.2. Mixtures

Description: Preparation: composed of the substances listed below.

Dangerous components:

CAS: 9002-93-1 Polyethylene glycol octylphenol ether <5%

 Acute Tox. 3, H311;  Aquatic Chronic 2, H411;  Acute Tox. 4, H302; Eye Irrit. 2, H319

SVHC Not applicable

The wording of the listed hazard warnings can be found in Section 16.

Substances that are on the "Candidate List of Substances of Very High Concern (SVHC) for authorization by the European Chemicals Agency (ECHA) are not intended to be part of this product. It is therefore not to be expected that these substances are contained in the product in quantities of > 0.1 %.

Section 4. First aid measures

4.1. Description of first aid measures

Following inhalation:

Provide fresh air; consult a doctor in case of medical complaints.

Following skin contact:

Generally, the product does not irritate the skin.

Following eye contact:

Rinse opened eye for several minutes under running water. Then consult a doctor.

Following ingestion:

Do not induce vomiting; call for medical help immediately.

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

No further relevant information is available.

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

No further relevant information is available.

Section 5. Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media:

Use fire extinguishing methods suitable to surrounding conditions.

Unsuitable extinguishing media:

No further relevant information is available.

5.2. Special hazards arising from the substance or mixture

No further relevant information is available.

5.3. Advice for firefighters

Protective equipment: No special measures required.

Section 6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Safety Data Sheet

According to Regulation (EU) No. 1907/2006 (REACH)

Product Name: Dialys-EO

Version: 03

Date: September 19, 2024



For non-emergency personnel:

No other relevant information available.

For emergency responders:

No other relevant information available.

6.2. Environmental precautions

Do not allow product to reach sewage system or any water course.

Inform respective authorities in case of seepage into water course or sewage system. Dilute with plenty of water.

Do not allow the product to enter sewers/ surface water or ground water.

6.3. Methods and material for containment and cleaning up

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

6.4. Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protective equipment.

See Section 13 for disposal information.

Section 7. Handling and storage

7.1. Precautions for safe handling

No special precautions are necessary if used correctly.

Information about fire - and explosion protection: No special measures required.

7.2. Conditions for safe storage, including any incompatibilities

Storage:

Requirements to be met by storerooms and receptacles: No special requirements.

Information about storage in one common storage facility: Not required.

Further information about storage conditions: Protect from frost.

7.3. Specific end use(s):

No further relevant information available.

Section 8. Exposure controls/personal protection

8.1. Control parameters

Ingredients with limit values that require monitoring at the workplace:

The product does not contain any significant quantities of materials with critical values that have to be monitored at the workplace.

Additional information:

The most current valid lists have been used as a basis for the production of this document.

8.2. Exposure controls

Appropriate engineering controls

No further data; see section 7.

Individual protection measures, such as personal protective equipment

General protective and hygienic measures: Wash hands before breaks and at the end of work.

Respiratory protection: No special measures required.

Hand protection: No special measures required.

Gloves material: Not applicable

Eye/face protection: Goggles recommended during refilling.

Environmental exposure controls

No further data available.

Safety Data Sheet

According to Regulation (EU) No. 1907/2006 (REACH)

Product Name: Dialys-EO

Version: 03

Date: September 19, 2024

Section 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties:

Parameter	Value / test method / remarks
Physical State	Liquid
Colour	Colourless
Odour	Odourless
Odour threshold	Not determined
Melting point / freezing point	0 °C
Boiling point or initial boiling point and boiling range	100 °C (CAS: 7732-18-5 water, distilled, conductivity or of similar purity)
Flammability	Not applicable.
Lower and upper explosion limit	Not determined.
Flash point	Not applicable.
Auto-ignition temperature	Not applicable.
Decomposition temperature	Not determined.
pH at 20 °C	6.80+/-10%
Kinematic viscosity	Not determined.
Dynamic at 20 °C	0.952 mPas
Solubility in water / in other solvents	Fully miscible.
Partition coefficient n-octanol/water (log value)	Not determined.
Vapour pressure at 20 °C	23 hPa (CAS: 7732-18-5 water, distilled, conductivity or of similar purity)
Density and/or relative density	Not determined.
Relative vapour density	Not determined.

9.2. Other information

Information with regard to physical hazard classes:

Explosives: Not classified as hazardous

Flammable gases: Not classified as hazardous

Aerosols: Not classified as hazardous

Oxidising gases: Not classified as hazardous

Gases under pressure: Not classified as hazardous

Flammable liquids: Not classified as hazardous

Flammable solids: Not classified as hazardous

Self-reactive substances and mixtures: Not classified as hazardous

Pyrophoric liquids: Not classified as hazardous

Pyrophoric solids: Not classified as hazardous

Self-heating substances and mixtures: Not classified as hazardous

Substances and mixtures, which emit flammable gases in contact with water: Not classified as hazardous

Oxidising liquids: Not classified as hazardous

Oxidising solids: Not classified as hazardous

Organic peroxides: Not classified as hazardous

Corrosive to metals: Not classified as hazardous

Desensitised explosives: Not classified as hazardous

Other safety characteristics:

Important information on protection of health and environment, and on safety. Osmolarity: 130 +/-10%

Ignition temperature: Product is not self igniting.

Explosive properties: Product does not present an explosion hazard.

Solvent content: 0.00 %

COV (USA) : 0.00 %

COV (CH) :

Change in condition

Evaporation rate : Not determined.

Section 10. Stability and reactivity

10.1. Reactivity

Safety Data Sheet

According to Regulation (EU) No. 1907/2006 (REACH)

Product Name: Dialys-EO

Version: 03

Date: September 19, 2024

No further relevant information available.

10.2. Chemical stability

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

10.3. Possibility of hazardous reactions

No dangerous reactions known.

10.4. Conditions to avoid

No further relevant information available.

10.5. Incompatible materials

No further relevant information available.

10.6. Hazardous decomposition products

No dangerous decomposition products known.

Section 11. Toxicological information

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

Summaries of the information derived from the test conducted:

Acute toxicity Based on available data, the classification criteria are not met.

LD/LC50 values relevant for classification:

CAS: 9002-93-1 Polyethylene glycol octylphenol ether

Oral LD50 1,800 mg/kg (rat)

Dermal LD50 500 mg/kg (rabbit)

On the skin: Based on available data, the classification criteria are not met.

On the eyes: Based on available data, the classification criteria are not met.

Respiratory or skin sensitization 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.

11.2. Information on other hazards

Endocrine disrupting properties

CAS: 9002-93-1 Polyethylene glycol octylphenol ether: List I

Section 12. Ecological information

12.1. Toxicity

Aquatic toxicity: No further relevant information available.

12.2. Persistence and degradability

No further relevant information available.

12.3. Bioaccumulative potential

No further relevant information available.

12.4. Mobility in soil

No further relevant information available.

12.5. Results of PBT and vPvB assessment

Safety Data Sheet

According to Regulation (EU) No. 1907/2006 (REACH)

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Version: 03

Date: September 19, 2024

PBT: Not applicable.

vPvB: Not applicable.

12.6. Endocrine disrupting properties

For information on endocrine disrupting properties see section 11.

12.7. Other adverse effects

No further relevant information available.

Remark: Harmful to fish

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.

Harmful to aquatic organisms

Section 13. Disposal considerations

13.1. Waste treatment methods

Information regarding the disposal of the product:



Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

European waste catalogue

HP6 Acute Toxicity

HP14 Ecotoxic

Uncleaned packaging:

Recommendation: Disposal must be made according to official regulations.

Recommended cleansing agents: Water, if necessary together with cleansing agents.

Section 14. Transport information

14.1. UN number or ID number

DOT, ADR, IMDG, IATA none

14.2. UN proper shipping name

ADR, IMDG, IATA none

14.3. Transport hazard class(es)

ADR, ADN, IMDG, IATA none

Class

14.4. Packing group

ADR, IMDG, IATA none

14.5. Environmental hazards

Not applicable.

14.6. Special precautions for user

Not applicable.

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

UN "Model Regulation": none

Safety Data Sheet

According to Regulation (EU) No. 1907/2006 (REACH)

Product Name: Dialys-EO

Version: 03

Date: September 19, 2024



Section 15. Regulatory information

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

Poisons Act

Regulated explosives precursors

None of the ingredients is listed.

Regulated poisons

None of the ingredients is listed.

Reportable explosives precursors

None of the ingredients is listed.

Reportable poisons

CAS: 1310-73-2 sodium hydroxide: 12% of total caustic alkalinity

Directive 2012/18/EU

Named dangerous substances - ANNEX I None of the ingredients is listed.

LIST OF SUBSTANCES SUBJECT TO AUTHORISATION (ANNEX XIV)

CAS: 9002-93-1 Polyethylene glycol octylphenol ether: Sunset date: 2021-01-04

LIST OF SUBSTANCES SUBJECT TO AUTHORISATION (UK ANNEX XIV)

CAS: 9002-93-1 Polyethylene glycol octylphenol ether: Sunset date: 2021-01-04

REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3

DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II

None of the ingredients is listed.

REGULATION (EU) 2019/1148

Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))

None of the ingredients is listed.

AnnexII- REPORTABLE EXPLOSIVES PRECURSORS

None of the ingredients is listed.

Regulation (EC) No 273/2004 on drug precursors

None of the ingredients is listed.

Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors

None of the ingredients is listed.

National regulations:

Substances of very high concern (SVHC) according to UK REACH

CAS: 9002-93-1 Polyethylene glycol octylphenol ether

15.2. Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

Section 16. Other information

Reason of Change:

Classification in accordance with Delegated Regulation (EU) 2022/692 of 16 February 2022 adapting to technical and scientific progress GB CLP for the 18th time and amending table 3 of Annex VI part 3 of Regulation (EC) 1272/2008.

Classification in accordance with Delegated Regulation (EU) 2023/1434 of 25 April 2023 adapting to technical and scientific progress for the 19th time GB CLP and amending Annex VI part 1, section 1.1.3 of Regulation (EC) 1272/2008.

Classification in accordance with Delegated Regulation (EU) 2023/1435 of 2 May 2023 adapting to technical and scientific progress for the 20th time GB CLP and amending Annex VI part 3 of Regulation (EC) 1272/2008.

This Safety Data Sheet is in compliance with Regulation (EC) No 1907/2006, Article 31 as amended by Regulation (EU) 2020/878.

Safety Data Sheet

According to Regulation (EU) No. 1907/2006 (REACH)

Product Name: Dialys-EO

Version: 03

Date: September 19, 2024



Relevant phrases

H302 Harmful if swallowed.

H311 Toxic in contact with skin.

H319 Causes serious eye irritation.

H411 Toxic to aquatic life with long lasting effects

Hazard statements mentioned in Sections 2 and 3:

Directive (EC) 127/2008:

Hazardous to the aquatic environment - long-term (chronic) aquatic hazard

The classification of the mixture is generally based on the calculation method using substance data according to Regulation (EC) No 1272/2008.

Dialab GmbH provides the information in this data sheet in good faith, declaring it is up to date at time of revision. However, this document is intended only as a guide for professional use, according to the intended purposes of the product. It does not represent a guarantee for the properties of the product described in terms of the legal warranty regulations.

Version number of previous version: 2

Abbreviations and acronyms:

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods DOT:

US Department of Transportation

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

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)

VOCV: Lenkungsabgabe auf flüchtigen organischen Verbindungen, Schweiz (Swiss Ordinance on volatile organic compounds) VOC:

Volatile Organic Compounds (USA, EU)

LC50: Lethal concentration, 50 percent LD50:

Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

SVHC: Substances of Very High Concern vPvB:

very Persistent and very Bioaccumulative Acute

Tox. 4: Acute toxicity – Category 4

Acute Tox. 3: Acute toxicity – Category 3

Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2 Aquatic

Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3