

# Safety data sheet

## according to 1907/2006/EC, Article 31

Printing date 21.09.2023

Version number 6 (replaces version 5)

Revision: 21.09.2023

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

- **1.1 Product identifier**
  - **Trade name:** Dialysis concentrate ECOCART
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**  
No further relevant information available.
  - **Application of the substance / the mixture** Dialysis concentrate
- **1.3 Details of the supplier of the safety data sheet**
  - **Manufacturer/Supplier:**  
Intermedt Medizin & Technik GmbH  
Gewerbestraße-Süd 13  
D-26842 Ostrhauderfehn  
Germany
  - **Informing department:**  
Tel.: +49 (0) 4952-82691-0  
info@Intermedt.de
- **1.4 Emergency telephone number:**  
Phone +49 (0) 4952-82691-0  
(Office hours 9:00 - 16:00)

### SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
  - **Classification according to Regulation (EC) No 1272/2008**  
The product is not classified, according to the GB CLP regulation.
- **2.2 Label elements**
  - **Labelling according to Regulation (EC) No 1272/2008** Void
    - **Hazard pictograms** Void
    - **Signal word** Void
    - **Hazard statements** Void
- **2.3 Other hazards**
  - **Results of PBT and vPvB assessment**
    - **PBT:** Not applicable.
    - **vPvB:** Not applicable.

### SECTION 3: Composition/information on ingredients

- **3.2 Mixtures**
  - **Description:** Mixture of the substances listed below including additives not requiring identification.

#### Dangerous components:

CAS: 10043-52-4 EINECS: 233-140-8 Reg.nr.: 01-2119494219-28-X	calcium chloride ⚠ Eye Irrit. 2, H319	≥ 2.5 - < 10%
CAS: 77-92-9 EINECS: 201-069-1 Reg.nr.: 01-2119457026-42-X	citric acid ⚠ Eye Irrit. 2, H319; STOT SE 3, H335	< 2.5%
CAS: 64-19-7 EINECS: 200-580-7 Reg.nr.: 01-2119475328-30-X	acetic acid ⚠ Flam. Liq. 3, H226; ⚠ Skin Corr. 1A, H314 Specific concentration limits: Skin Corr. 1A; H314: C ≥ 90 % Skin Corr. 1B; H314: 25 % ≤ C < 90 % Skin Irrit. 2; H315: 10 % ≤ C < 25 % Eye Irrit. 2; H319: 10 % ≤ C < 25 %	< 2.5%

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- **Additional information** For the wording of the listed hazard phrases refer to section 16.

### SECTION 4: First aid measures

- **4.1 Description of first aid measures**
  - **General information** No special measures required.
  - **After inhalation** Supply fresh air; consult doctor in case of symptoms.
  - **After skin contact** Wash with water and soap.
  - **After eye contact** Rinse opened eye for several minutes under running water.
  - **After swallowing**  
Rinse out mouth and then drink plenty of water.  
In case of persistent symptoms consult doctor.
- **4.2 Most important symptoms and effects, both acute and delayed**  
No further relevant information available.
- **4.3 Indication of any immediate medical attention and special treatment needed**  
No further relevant information available.

### SECTION 5: Firefighting measures

- **5.1 Extinguishing media**
  - **Suitable extinguishing agents**  
The product itself does not burn.  
Use fire fighting measures that suit the environment.
  - **For safety reasons unsuitable extinguishing agents** None known.
- **5.2 Special hazards arising from the substance or mixture**  
Can be released in case of fire:  
Carbon monoxide (CO)
- **5.3 Advice for firefighters**
  - **Protective equipment:**  
Do not inhale explosion gases or combustion gases.  
Use a breathing apparatus that is independent of circulating air when being in closed rooms.

### SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**  
Avoid causing dust.  
Ensure adequate ventilation
  - **For non-emergency personnel** Avoid contact with the product.
  - **For emergency responders** Put on suitable personal protective equipment.
- **6.2 Environmental precautions:** Do not allow to enter drainage system, surface or ground water.
- **6.3 Methods and material for containment and cleaning up:**  
Collect mechanically.  
Dispose of the material collected according to regulations.  
Clean the accident area carefully; suitable cleaners are:  
warm water
- **6.4 Reference to other sections**  
See Section 7 for information on safe handling  
See Section 8 for information on personal protection equipment.  
See Section 13 for information on disposal.

### SECTION 7: Handling and storage

- **7.1 Precautions for safe handling** Provide suction extractors if dust is formed.

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- **Information about protection against explosions and fires:** No special measures required.
- **Handling** Wash hands during breaks and at the end of the work.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage**
  - **Requirements to be met by storerooms and containers:** Store under dry conditions.
  - **Information about storage in one common storage facility:**
    - Store away from oxidising agents.
  - **Further information about storage conditions:**
    - Keep container tightly sealed.
    - Store under dry conditions.
- **7.3 Specific end use(s)** No further relevant information available.

### SECTION 8: Exposure controls/personal protection

- **8.1 Control parameters**
- **Components with limit values that require monitoring at the workplace:**
  - WEL: workplace exposure limit
  - OEL: Occupational Exposure Limit

#### 64-19-7 acetic acid

WEL (Great Britain)	Short-term value: 50 mg/m <sup>3</sup> , 20 ppm Long-term value: 25 mg/m <sup>3</sup> , 10 ppm
IOELV (European Union)	Short-term value: 50 mg/m <sup>3</sup> , 20 ppm Long-term value: 25 mg/m <sup>3</sup> , 10 ppm
OEL (Ireland)	Short-term value: 50 mg/m <sup>3</sup> , 20 ppm Long-term value: 25 mg/m <sup>3</sup> , 10 ppm IOELV

#### · DNELs

#### 10043-52-4 calcium chloride

Inhalative	DNEL (worker, short-term, local)	10 mg/m <sup>3</sup> (human)
	DNEL (worker, long-term, local)	5 mg/m <sup>3</sup> (human)
	DNEL (consumer, short-term, local)	5 mg/m <sup>3</sup> (human)
	DNEL (consumer, long-term, local)	2.5 mg/m <sup>3</sup> (human)

#### 64-19-7 acetic acid

Inhalative	DNEL (worker, short-term, local)	25 mg/m <sup>3</sup> (human)
	DNEL (worker, long-term, local)	25 mg/m <sup>3</sup> (human)
	DNEL (consumer, short-term, local)	25 mg/m <sup>3</sup> (human)
	DNEL (consumer, long-term, local)	25 mg/m <sup>3</sup> (human)

#### · PNECs

#### 64-19-7 acetic acid

PNEC aqua (freshwater)	3.058 mg/L (.)
PNEC aqua (marine water)	0.3058 mg/L (.)
PNEC STP - Sewage Treatment Plant	85 mg/L (.)
PNEC soil	0.47 mg/kg soil dw (.)
PNEC sediment (freshwater)	11.36 mg/kg sedim. dw (.)
PNEC sediment (marine water)	1.136 mg/kg sedim. dw (.)
PNEC aqua (intermittent releases)	30.58 mg/L (.)

- **Additional information:** The lists that were valid during the compilation were used as basis.

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- **8.2 Exposure controls**
- **Individual protection measures, such as personal protective equipment**
- **General protective and hygienic measures**  
The usual precautionary measures should be adhered to general rules for handling chemicals.
- **Breathing equipment:** Not required when used as intended.
- **Hand protection**  
To avoid skin contact and for the protection of the product gloves made of synthetic rubber can be worn.
  - **Material of gloves** Synthetic rubber gloves
  - **Penetration time of glove material**  
With solid dry substances permeation is not to be expected. Therefore the breakthrough-time for this protective glove has not been measured.  
With a lamination strength of 0,11 mm the permeation time is > 480 min.  
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
  - **For the permanent contact gloves made of the following materials are suitable:**  
Nitrile rubber, NBR
- **Eye/face protection** Safety glasses recommended during refilling.

### SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**
- **General Information**
- **Colour:** White
- **Odour:** where appropriate:  
slight acetic  
possibly slight acetic
- **Melting point/freezing point:** Not determined
- **Boiling point or initial boiling point and boiling range** Not determined
- **Flash point:** Not applicable
- **SADT**
- **pH at 20 °C** 2.5
- **Solubility**
- **Water:** Soluble
- **Density and/or relative density**
- **Density** Not determined
- **9.2 Other information**
- **Appearance:**
- **Form:** Solid
- **Important information on protection of health and environment, and on safety.**
- **Self-inflammability:** Product is not selfigniting.
- **Explosive properties:** Product is not explosive. However, formation of explosive air/dust mixtures is possible.
- **Information with regard to physical hazard classes**
- **Explosives** Void
- **Flammable gases** Void
- **Aerosols** Void
- **Oxidising gases** Void
- **Gases under pressure** Void
- **Flammable liquids** Void
- **Flammable solids** Void

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· <b>Self-reactive substances and mixtures</b>	Void
· <b>Pyrophoric liquids</b>	Void
· <b>Pyrophoric solids</b>	Void
· <b>Self-heating substances and mixtures</b>	Void
· <b>Substances and mixtures, which emit flammable gases in contact with water</b>	Void
· <b>Oxidising liquids</b>	Void
· <b>Oxidising solids</b>	Void
· <b>Organic peroxides</b>	Void
· <b>Corrosive to metals</b>	Void
· <b>Desensitised explosives</b>	Void

### SECTION 10: Stability and reactivity

- **10.1 Reactivity** 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:** Avoid contact with strong oxidizing agents.
- **10.6 Hazardous decomposition products:**  
None in case of intended use and storage in compliance with instructions.

### SECTION 11: Toxicological information

- **11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008**
- **Acute toxicity** Based on available data, the classification criteria are not met.

#### · **LD/LC50 values that are relevant for classification:**

##### 10043-52-4 calcium chloride

Oral	LD50	2,301 mg/kg (rat) (OECD 401)
Dermal	LD50	> 5,000 mg/kg (rabbit)
Inhalative	LC50	> 0.16 mg/l/4h (rat)

##### 77-92-9 citric acid

Oral	LD50	5,400 mg/kg (mouse) (OECD 401)
		5,790 mg/kg (rat) (OECD 401)
Dermal	LD50	> 2,000 mg/kg (rat) (OECD 402)

##### 64-19-7 acetic acid

Oral	LD50	3,310 mg/kg (rat)
Inhalative	LC50	13,825 mg/l/1h (mouse)
	LC50	> 40,000 mg/l/4h (rat)

- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation** Splashes can cause temporary eye irritation.
- **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.

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**· Additional toxicological information:**
**· Repeated dose toxicity**
**10043-52-4 calcium chloride**
Oral NOAEL (28d)  $\geq$  1,000 mg/kg bw/day (rat)
**· 11.2 Information on other hazards**
**· Endocrine disrupting properties**

None of the ingredients is listed.

## SECTION 12: Ecological information

**· 12.1 Toxicity**
**· Aquatic toxicity:**
**77-92-9 citric acid**

EC50 (static) 1,535 mg/l/24h (Daphnia magna)

EC50 (static) 440 mg/l/48h (fish) (OECD 203)

**64-19-7 acetic acid**

EC50 (static) &gt; 1,000 mg/l/48h (Daphnia magna) (OECD 2B2)

LC50 &gt; 1,000 mg/l/96h (Oncorhynchus mykiss) (OECD 203)

EC50 (static) &gt; 1,000 mg/l/72h (Skeletonema costatum) (ISO 10253)

**· 12.2 Persistence and degradability** No further relevant information available.

**· 12.3 Bioaccumulative potential** Due to good water solubility, expect no bioaccumulation.

**· 12.4 Mobility in soil** No further relevant information available.

**· 12.5 Results of PBT and vPvB assessment**
**· PBT:** Not applicable.

**· vPvB:** Not applicable.

**· 12.6 Endocrine disrupting properties**

The product does not contain substances with endocrine disrupting properties.

**· 12.7 Other adverse effects**
**· Additional ecological information:**
**· General notes:**

Do not allow undiluted product or large quantities of it to reach ground water, water bodies or sewage system.

## SECTION 13: Disposal considerations

**· 13.1 Waste treatment methods**
**· Recommendation**

Smaller quantities can be disposed with household waste.

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

The waste code numbers mentioned are recommendations based on the probable use of the product.

**· European waste catalogue**

07 00 00 WASTES FROM ORGANIC CHEMICAL PROCESSES

07 05 00 wastes from the MFSU of pharmaceuticals

07 05 14 solid wastes other than those mentioned in 07 05 13

16 00 00 WASTES NOT OTHERWISE SPECIFIED IN THE LIST

16 03 00 off-specification batches and unused products

16 03 06 organic wastes other than those mentioned in 16 03 05

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- **Uncleaned packagings:**
- **Recommendation:**  
Non contaminated packagings can be reused.  
Dispose of packaging according to regulations on the disposal of packagings.  
Non contaminated packagings can be used for recycling.
- **Recommended cleaning agent:** Water, if necessary with cleaning agent.

### SECTION 14: Transport information

- |   |  |
|---|--|
| <ul style="list-style-type: none"> <li>· <b>14.1 UN number or ID number</b></li> <li>· <b>ADR/RID, ADN, IMDG, IATA</b></li> </ul>                             | Void   |
| <ul style="list-style-type: none"> <li>· <b>14.2 UN proper shipping name</b></li> <li>· <b>ADR/RID, ADN, IMDG, IATA</b></li> </ul>                            | Void   |
| <ul style="list-style-type: none"> <li>· <b>14.3 Transport hazard class(es)</b></li> <li>· <b>ADR/RID, ADN, IMDG, IATA</b></li> <li>· <b>Class</b></li> </ul> | Void   |
| <ul style="list-style-type: none"> <li>· <b>14.4 Packing group</b></li> <li>· <b>ADR/RID, IMDG, IATA</b></li> </ul>   | Void   |
| <ul style="list-style-type: none"> <li>· <b>14.5 Environmental hazards:</b></li> <li>· <b>Marine pollutant:</b></li> </ul>                                    | No   |
| <ul style="list-style-type: none"> <li>· <b>14.6 Special precautions for user</b></li> </ul>  | Not applicable.                                      |
| <ul style="list-style-type: none"> <li>· <b>14.7 Maritime transport in bulk according to IMO instruments</b></li> </ul>                                       | Not applicable.                                      |
| <ul style="list-style-type: none"> <li>· <b>Transport/Additional information:</b></li> </ul>  | Not dangerous according to the above specifications. |
| <ul style="list-style-type: none"> <li>· <b>UN "Model Regulation":</b></li> </ul>   | Void   |

### SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Chemical safety assessment**
- **Named dangerous substances - ANNEX I** 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.

· **Annex II - REPORTABLE EXPLOSIVES PRECURSORS**

None of the ingredients is listed.

- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

### SECTION 16: Other information

These data are based on our present knowledge. However, they shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- **Relevant phrases**

The phrases specified here are no labelling elements for the product but repeat the properties of the ingredients from section 3.

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H226 Flammable liquid and vapour.  
 H314 Causes severe skin burns and eye damage.  
 H319 Causes serious eye irritation.  
 H335 May cause respiratory irritation.

· **Department issuing data specification sheet:**

► **DEKRA** This Safety Data Sheet has been drawn up in cooperation with:  
 DEKRA Assurance Services GmbH, Hanomagstr. 12, D-30449 Hanover, Germany,  
 phone: (+49) 511 42079 - 0, reach@dekra.com.

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· **Abbreviations and acronyms:**

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)  
 ICAO: International Civil Aviation Organisation  
 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  
 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)  
 DNEL: Derived No-Effect Level (UK REACH)  
 PNEC: Predicted No-Effect Concentration (UK REACH)  
 LC50: Lethal concentration, 50 percent  
 LD50: Lethal dose, 50 percent  
 PBT: Persistent, Bioaccumulative and Toxic  
 vPvB: very Persistent and very Bioaccumulative  
 Flam. Liq. 3: Flammable liquids – Category 3  
 Skin Corr. 1A: Skin corrosion/irritation – Category 1A  
 Eye Irrit. 2: Serious eye damage/eye irritation – Category 2  
 STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

· **\* Data compared to the previous version altered.**

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