



# SAFETY DATA SHEET

Revision date 16-Jun-2025

Version 3

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## Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

### 1.1. Product identifier

**Product Name** PLEGISOL (Cardioplegic Solution)  
**Product Code(s)** PZ02949  
**Trade Name:** PLEGISOL  
**Chemical Family:** Mixture

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

**Recommended Use** Pharmaceutical product used as electrolyte replacement

### 1.3. Details of the supplier of the safety data sheet

Pfizer Inc  
66 Hudson Boulevard East  
New York, New York 10001  
1-800-879-3477

Pfizer Ireland Pharmaceuticals  
OSG Building  
Ringaskiddy, Co. Cork.  
Ireland  
+353 21 4378701

**E-mail address** pfizer-MSDS@pfizer.com

### 1.4. Emergency telephone number

**Emergency Telephone** Chemtrec 1-800-424-9300 International Chemtrec (24 hours):+1-703-527-3887

## Section 2: HAZARDS IDENTIFICATION

### 2.1. Classification of the substance or mixture

GHS - Classification: This substance is classified as not hazardous according to regulation (EC) 1272/2008 [CLP].

#### OSHA Classification

##### Hazards not otherwise classified (HNOC)

Not applicable

##### Hazards classified under paragraph (d)(1)(ii) of 1910.1200

Not applicable

### 2.2. Label elements

**Signal word** Not classified

**Hazard statements** Not classified in accordance with international standards for workplace safety.

### 2.3. Other hazards

**Other hazards** An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

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## PBT & vPvB

The product does not contain any substance(s) classified as PBT or vPvB.

## Endocrine Disruptor Information

This product does not contain any known or suspected endocrine disruptors.

## Note:

This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

## Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 Substances

#### Substances

Not applicable

### 3.2 Mixtures

#### Hazardous

Chemical name	Weight-%	REACH registration number	EC No (EU Index No)	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Calcium chloride USP (CAS #: 10035-04-8)	<1.0		Not Listed	Eye Irrit. 2 (H319)	Not classified	No data available	No data available

#### NonHazardous

Chemical name	Weight-%	REACH registration number	EC No (EU Index No)	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Water (CAS #: 7732-18-5)	*	-	231-791-2	Not classified	Not classified	No data available	No data available
SODIUM CHLORIDE (CAS #: 7647-14-5)	*	-	231-598-3	Not classified	Not classified	No data available	No data available
Magnesium chloride hexahydrate (CAS #: 7791-18-6)	*		Not Listed	Not classified	Not classified	No data available	No data available
POTASSIUM CHLORIDE (CAS #: 7447-40-7)	*		231-211-8	Acute Tox 5 (H303)	Not classified	No data available	No data available

## Full text of H- and EUH-phrases: see section 16

## Acute Toxicity Estimate

Chemical name	Oral LD50 mg/kg	Dermal LD50 mg/kg	Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapor - mg/L	Inhalation LC50 - 4 hour - gas - ppm
Water 7732-18-5	89838.9	No data available	No data available	No data available	No data available
SODIUM CHLORIDE	3550	10000	No data available	No data available	No data available

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Chemical name	Oral LD50 mg/kg	Dermal LD50 mg/kg	Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapor - mg/L	Inhalation LC50 - 4 hour - gas - ppm
7647-14-5					
Magnesium chloride hexahydrate 7791-18-6	8100	No data available	No data available	No data available	No data available
POTASSIUM CHLORIDE 7447-40-7	3020	No data available	No data available	No data available	No data available
Calcium chloride USP 10035-04-8	1000	No data available	No data available	No data available	No data available

This product does not contain candidate substances of very high concern at a concentration  $\geq 0.1\%$  (Regulation (EC) No. 1907/2006 (REACH), Article 59).

## Additional information

\* Proprietary

Non-hazardous ingredients provided for completeness. Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

## Section 4: FIRST AID MEASURES

### 4.1. Description of first aid measures

Inhalation	Not an expected route of exposure.
Eye contact	If symptoms persist, call a physician.
Skin contact	Due to the nature of this material first aid is not normally required.
Ingestion	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

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

Most important symptoms and effects	No data available
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### 4.3. Indication of any immediate medical attention and special treatment needed

Note to physicians	None.
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## Section 5: FIRE-FIGHTING MEASURES

### 5.1. Extinguishing media

Suitable Extinguishing Media	Dry chemical, CO2, alcohol-resistant foam or water spray.
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### 5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the chemical	Not applicable.
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Hazardous combustion products	Not applicable
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### Explosion data

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**Sensitivity to mechanical impact** No information available.

**Sensitivity to static discharge** No information available.

## 5.3. Advice for firefighters

**Special protective equipment and precautions for fire-fighters** Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

## Section 6: ACCIDENTAL RELEASE MEASURES

### 6.1. Personal precautions, protective equipment and emergency procedures

**Personal precautions** Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

**For emergency responders** Use personal protection recommended in Section 8.

### 6.2. Environmental precautions

**Environmental precautions** Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

### 6.3. Methods and material for containment and cleaning up

**Methods for containment** Prevent further leakage or spillage if safe to do so.

**Methods for cleaning up** Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

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

### 6.4. Reference to other sections

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

## Section 7: HANDLING AND STORAGE

### 7.1. Precautions for safe handling

**Advice on safe handling** None under normal use conditions.

**General hygiene considerations** Handle in accordance with good industrial hygiene and safety practice.

### 7.2. Conditions for safe storage, including any incompatibilities

**Storage Conditions** Store as directed by product packaging.

### 7.3. Specific end use(s)

**Specific use(s)** Pharmaceutical drug product.

## Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1. Control parameters

#### Exposure Limits

Refer to available public information for specific member state Occupational Exposure Limits.

#### SODIUM CHLORIDE

Latvia

Russia

TWA: 5 mg/m<sup>3</sup>;

MAC: 5 mg/m<sup>3</sup>

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## Magnesium chloride hexahydrate

Russia

MAC: 2 mg/m<sup>3</sup>

## POTASSIUM CHLORIDE

Bulgaria

TWA: 5.0 mg/m<sup>3</sup>;

Latvia

TWA: 5 mg/m<sup>3</sup>;

Russia

MAC: 5 mg/m<sup>3</sup>

## Calcium chloride USP

Pfizer Occupational Exposure  
Band (OEB):

OEB 2 - Severe Eye Irritant (control exposure to the range of 100ug/m<sup>3</sup> to < 1000ug/m<sup>3</sup>, provide additional precautions to protect from skin contact)

## 8.2. Exposure controls

### Engineering controls

Engineering controls should be used as the primary means to control exposures.

### Personal protective equipment

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

### Eye/face protection

Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.).

### Hand protection

Impervious disposable gloves (e.g. Nitrile, etc.) (double recommended) if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.).

### Skin and body protection

Wear impervious protective clothing to prevent skin contact – consider use of disposable clothing where appropriate. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.).

### Respiratory protection

Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent.).

### Thermal hazards

No information available.

### Environmental exposure controls

No information available.

## Section 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1. Information on basic physical and chemical properties

#### Physical state

Liquid

#### Color

Colorless

#### Odor

No information available.

#### Odor threshold

No information available

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<u>Property</u>	<u>Values</u>
Melting point / freezing point	No data available
Boiling point or initial boiling point and boiling range	No data available
Flammability (solid, gas)	No data available
Lower and upper explosion limit/flammability limit	
Lower explosion limit	No data available
Upper explosion limit	No data available
Flash point	No data available
Autoignition temperature	No data available
Decomposition temperature	
SADT (°C)	No data available
pH	No data available
pH (as aqueous solution)	No data available
Kinematic viscosity	No data available
Dynamic viscosity	No data available
Solubility	No data available
Vapor pressure	No data available
Density and/or relative density	No data available
Bulk density	No data available
Liquid Density	No data available
Vapor density	No data available
Particle characteristics	
Particle Size	No information available
Particle Size Distribution	No information available

## 9.2. Other information

Molecular formula	Mixture
Molecular weight	Mixture

### 9.2.1. Information with regard to physical hazard classes

No information available

### 9.2.2. Other safety characteristics

No information available

## **Section 10: STABILITY AND REACTIVITY**

### 10.1. Reactivity

Reactivity No information available.

### 10.2. Chemical stability

Stability Stable under normal conditions.

### Explosion data

Sensitivity to mechanical impact No information available.

Sensitivity to static discharge No information available.

### 10.3. Possibility of hazardous reactions

Possibility of hazardous reactions No information available.

### 10.4. Conditions to avoid

Conditions to avoid Fine particles (such as dust and mists) may fuel fires/explosions.

### 10.5. Incompatible materials

Incompatible materials As a precautionary measure, keep away from strong oxidizers.

### 10.6. Hazardous decomposition products

Hazardous decomposition products No data available.

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## Section 11: TOXICOLOGICAL INFORMATION

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

**General Information:** The information included in this section describes the potential hazards of the individual ingredients

<b>Acute toxicity</b>	Based on available data, the classification criteria are not met.
<b>Serious eye damage/eye irritation</b>	Based on available data, the classification criteria are not met.
<b>Skin corrosion/irritation</b>	Based on available data, the classification criteria are not met.
<b>Respiratory or skin sensitization</b>	Based on available data, the classification criteria are not met.
<b>STOT - single exposure</b>	Based on available data, the classification criteria are not met.
<b>STOT - repeated exposure</b>	Based on available data, the classification criteria are not met.
<b>Reproductive toxicity</b>	Based on available data, the classification criteria are not met.
<b>Germ cell mutagenicity</b>	Based on available data, the classification criteria are not met.
<b>Carcinogenicity</b>	Based on available data, the classification criteria are not met.
<b>Aspiration hazard</b>	Based on available data, the classification criteria are not met.

#### **Acute Toxicity: (Species, Route, End Point, Dose)**

##### **SODIUM CHLORIDE**

Rat Sub-tenon injection (eye) LC50/1hr > 42 g/m<sup>3</sup>

Rat Oral LD50 3 g/kg

Mouse Oral LD50 4 g/kg

Rabbit Dermal LD50 > 10 g/kg

##### **POTASSIUM CHLORIDE**

Rat Oral LD50 3020 mg/kg

##### **Calcium chloride USP**

Rat Oral LD50 2301 mg/kg

Mouse Oral LD50 1940 mg/kg

Rabbit Dermal LD50 > 5000 mg/kg

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Water	> 90 mL/kg ( Rat )	-	-
SODIUM CHLORIDE	= 3550 mg/kg ( Rat )	> 10000 mg/kg ( Rabbit )	> 42 mg/L ( Rat ) 1 h
Magnesium chloride hexahydrate	= 8100 mg/kg ( Rat )	-	-
POTASSIUM CHLORIDE	= 2600 mg/kg ( Rat )	-	-

#### **Irritation / Sensitization: (Study Type, Species, Severity)**

##### **SODIUM CHLORIDE**

Skin irritation Rabbit Mild

Eye irritation Rabbit Mild

##### **POTASSIUM CHLORIDE**

Eye Irritation Rabbit Mild

##### **Calcium chloride USP**

Eye Irritation Rabbit Moderate

#### **Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)**

##### **Magnesium chloride hexahydrate**

13 Week(s) Mouse Oral 273 g/kg LOEL Kidney, Ureter, Bladder

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**Carcinogenicity** None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

## **11.2. Information on other hazards**

### **11.2.1. Endocrine disrupting properties**

**Endocrine disrupting properties** Based on available data, the classification criteria are not met.

### **11.2.2. Other information**

**Other adverse effects** No information available.

## **Section 12: ECOLOGICAL INFORMATION**

**Environmental Overview:** No harmful effects to aquatic organisms are expected. Releases to the environment should be avoided.

### **12.1. Toxicity**

#### **Aquatic Toxicity: (Species, Method, End Point, Duration, Result)**

##### **POTASSIUM CHLORIDE**

*Gambusia affinis* (Mosquitofish) LC50 96 hours 920 mg/L  
*Lepomis macrochirus* (Bluegill Sunfish) LC50 96 hours 2010 mg/L  
*Daphnia Magna* (Water Flea) EC50 48 hours 825 mg/L  
*Scenedesmus subspicatus* (Green Alga) EC50 72 hours 2500 mg/L

### **12.2. Persistence and degradability**

**Persistence and degradability** No information available.

### **12.3. Bioaccumulative potential**

**Bioaccumulation** No information available.

### **12.4. Mobility in soil**

**Mobility in soil** No information available.

### **12.5. Results of PBT and vPvB assessment**

#### **PBT and vPvB assessment**

Chemical name	PBT and vPvB assessment
SODIUM CHLORIDE	Not PBT/vPvB PBT assessment does not apply
POTASSIUM CHLORIDE	Not PBT/vPvB PBT assessment does not apply

### **12.6. Endocrine disrupting properties**

**Endocrine disrupting properties** Based on available data, the classification criteria are not met.



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## 12.7. Other adverse effects

**Other adverse effects**  
**PMT or vPvM properties**

No information available.  
Based on available data, the classification criteria are not met.

## Section 13: DISPOSAL CONSIDERATIONS

### 13.1. Waste treatment methods

#### Waste from residues/unused products

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural wastewater and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

## Section 14: TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

**Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.**

<b>UN number:</b>	Not applicable
<b>UN proper shipping name:</b>	Not applicable
<b>Transport hazard class(es):</b>	Not applicable
<b>Packing group:</b>	Not applicable
<b>Environmental Hazard(s):</b>	Not applicable

## Section 15: REGULATORY INFORMATION

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

Water

<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present
<b>EINECS</b>	231-791-2
<b>AICS</b>	Present

SODIUM CHLORIDE

<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present
<b>EINECS</b>	231-598-3
<b>AICS</b>	Present

Magnesium chloride hexahydrate

<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>EINECS</b>	Not Listed
<b>AICS</b>	Present

POTASSIUM CHLORIDE

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<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present
<b>EINECS</b>	231-211-8
<b>AICS</b>	Present
<b>Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)</b>	Schedule 4
Calcium chloride USP	
<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>EINECS</b>	Not Listed
<b>AICS</b>	Present

## National regulations

### France

#### Occupational Illnesses (R-463-3, France)

Chemical name	French RG number
SODIUM CHLORIDE 7647-14-5	RG 78
POTASSIUM CHLORIDE 7447-40-7	RG 67

### Germany

#### Chemical Prohibition Ordinance (ChemVerbotsV)

Not applicable

### TRGS 905

Not applicable

### Switzerland

**Ordinance on the Incentive Tax on Volatile Organic Compounds (OVOC) SR 814.018** Not applicable

**Storage of Hazardous Material** Not applicable

**WPO (GSchV) SR 814.201; WPA (GSchG) SR 814.20** Not applicable

**Major Accidents Ordinance SR 814.012** Not applicable

### European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.

#### Authorizations and/or restrictions on use:

This product does not contain substances subject to authorization (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

### Persistent Organic Pollutants

Not applicable

### Ozone-depleting substances (ODS) Regulation (EU) 2024/590

Not applicable.

### EU - Plant Protection Products (1107/2009/EC)

Chemical name	EU - Plant Protection Products (1107/2009/EC)
SODIUM CHLORIDE 7647-14-5	Plant protection agent

Chemical name	Biocidal Products Regulation (EU) No 528/2012 (BPR)
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SODIUM CHLORIDE 7647-14-5	Product-type 1: Human hygiene
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## Explosives Precursors Marketing and Use (2019/1148)

Not applicable

### Legend:

**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory

**DSL/NDSL** - Canadian Domestic Substances List/Non-Domestic Substances List

**EINECS/ELINCS** - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

**ENCS** - Japan Existing and New Chemical Substances

**IECSC** - China Inventory of Existing Chemical Substances

**KECL** - Korean Existing Chemicals Inventory

**PICCS** - Philippines Inventory of Chemicals and Chemical Substances

**AICS** - Australian Inventory of Chemical Substances

**NZIoC** - New Zealand Inventory of Chemicals

**TCSI** - Taiwan Chemical Substance Inventory

## 15.2. Chemical safety assessment

**Chemical Safety Report** No information available

## Section 16: OTHER INFORMATION

### Key or legend to abbreviations and acronyms used in the safety data sheet

### Full text of any hazard and/or precautionary statements referred to under Sections 2-15

H319 - Causes serious eye irritation

**Data Sources:** Publicly available toxicity information.

**Reason for revision** Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information. Updated Section 15 - Regulatory Information.

**Revision date** 16-Jun-2025

**Prepared By** Pfizer Global Environment, Health, and Safety

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