



# SAFETY DATA SHEET

Revision date: 14-Feb-2018

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## 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

### Product Identifier

**Material Name:** PLEGISOL (Cardioplegic Solution)

**Trade Name:** PLEGISOL

**Chemical Family:** Mixture

### Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

**Intended Use:** Pharmaceutical product used as electrolyte replacement

### Details of the Supplier of the Safety Data Sheet

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## 2. HAZARDS IDENTIFICATION

### Classification of the Substance or Mixture

**GHS - Classification** Not classified as hazardous

### Label Elements

**Signal Word:** Not Classified

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

### Other Hazards

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

### Note:

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

## 3. COMPOSITION / INFORMATION ON INGREDIENTS

### Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%

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### 3. COMPOSITION / INFORMATION ON INGREDIENTS

Calcium chloride USP	10035-04-8	Not Listed	Eye Irrit. 2 (H319)	<1.0
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Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
POTASSIUM CHLORIDE	7447-40-7	231-211-8	Not Listed	*
Water for injection	7732-18-5	231-791-2	Not Listed	*
Magnesium chloride hexahydrate	7791-18-6	Not Listed	Not Listed	*
Sodium chloride	7647-14-5	231-598-3	Not Listed	*

#### Additional Information:

\* Proprietary  
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.

For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16

### 4. FIRST AID MEASURES

#### Description of First Aid Measures

**Eye Contact:** If irritation occurs or persists, get medical attention. Flush eyes with water as a precaution

**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.

**Inhalation:** Not an expected route of exposure.

#### Most Important Symptoms and Effects, Both Acute and Delayed

**Symptoms and Effects of Exposure:** No data available

**Medical Conditions Aggravated by Exposure:** None known

#### Indication of the Immediate Medical Attention and Special Treatment Needed

**Notes to Physician:** None

### 5. FIRE FIGHTING MEASURES

**Extinguishing Media:** As for primary cause of fire.

#### Special Hazards Arising from the Substance or Mixture

**Hazardous Combustion Products:** Not applicable

**Fire / Explosion Hazards:** Not applicable

#### Advice for Fire-Fighters

Not applicable

### 6. ACCIDENTAL RELEASE MEASURES

#### Personal Precautions, Protective Equipment and Emergency Procedures

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### 6. ACCIDENTAL RELEASE MEASURES

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

#### Environmental Precautions

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

#### Methods and Material for Containment and Cleaning Up

**Measures for Cleaning / Collecting:** Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

**Additional Consideration for Large Spills:** Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Cleanup operations should only be undertaken by trained personnel.

### 7. HANDLING AND STORAGE

#### Precautions for Safe Handling

No special handling requirements for normal use of this material.

#### Conditions for Safe Storage, Including any Incompatibilities

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

**Specific end use(s):** Pharmaceutical drug product

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Control Parameters

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

#### POTASSIUM CHLORIDE

Bulgaria OEL - TWA 5.0 mg/m<sup>3</sup>

Latvia OEL - TWA 5 mg/m<sup>3</sup>

Lithuania OEL - TWA 5 mg/m<sup>3</sup>

#### Sodium chloride

Latvia OEL - TWA 5 mg/m<sup>3</sup>

Lithuania OEL - TWA 5 mg/m<sup>3</sup>

#### POTASSIUM CHLORIDE

**Pfizer Occupational Exposure Band (OEB):** OEB 1 (control exposure to the range of 1000ug/m<sup>3</sup> to 3000ug/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)

#### Sodium chloride

**Pfizer Occupational Exposure Band (OEB):** OEB 1 (control exposure to the range of 1000ug/m<sup>3</sup> to 3000ug/m<sup>3</sup>)

#### 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.

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<b>Hands:</b>	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.)
<b>Eyes:</b>	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.)
<b>Skin:</b>	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.)
<b>Respiratory protection:</b>	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.)

### 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Physical State:</b>	Liquid	<b>Color:</b>	Colorless
<b>Odor:</b>	No data available.	<b>Odor Threshold:</b>	No data available.
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture

<b>Solvent Solubility:</b>	No data available
<b>Water Solubility:</b>	No data available
<b>pH:</b>	No data available.
<b>Melting/Freezing Point (°C):</b>	No data available
<b>Boiling Point (°C):</b>	No data available.

**Partition Coefficient: (Method, pH, Endpoint, Value)**

**POTASSIUM CHLORIDE**

No data available

**Calcium chloride USP**

No data available

**Magnesium chloride hexahydrate**

No data available

**Sodium chloride**

No data available

**Water for injection**

No data available

**Decomposition Temperature (°C):** No data available.

<b>Evaporation Rate (Gram/s):</b>	No data available
<b>Vapor Pressure (kPa):</b>	No data available
<b>Vapor Density (g/ml):</b>	No data available
<b>Relative Density:</b>	No data available
<b>Viscosity:</b>	No data available

**Flammability:**

<b>Autoignition Temperature (Solid) (°C):</b>	No data available
<b>Flammability (Solids):</b>	No data available
<b>Flash Point (Liquid) (°C):</b>	No data available
<b>Upper Explosive Limits (Liquid) (% by Vol.):</b>	No data available
<b>Lower Explosive Limits (Liquid) (% by Vol.):</b>	No data available

### 10. STABILITY AND REACTIVITY

**Reactivity:** No data available

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### 10. STABILITY AND REACTIVITY

**Chemical Stability:** Stable under normal conditions of use.  
**Possibility of Hazardous Reactions**  
**Oxidizing Properties:** No data available  
**Conditions to Avoid:** Fine particles (such as dust and mists) may fuel fires/explosions.  
**Incompatible Materials:** As a precautionary measure, keep away from strong oxidizers  
**Hazardous Decomposition Products:** No data available

### 11. TOXICOLOGICAL INFORMATION

#### Information on Toxicological Effects

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

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

##### POTASSIUM CHLORIDE

Rat Oral LD50 2600 mg/kg

##### Calcium chloride USP

Rat Oral LD50 1000 mg/kg  
Mouse Oral LD50 1940mg/kg

##### Sodium chloride

Rat Oral LD50 3000 mg/kg  
Mouse Oral LD50 4000 mg/kg

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

##### POTASSIUM CHLORIDE

Eye Irritation Rabbit Mild

##### Calcium chloride USP

Eye Irritation Rabbit Moderate

##### Sodium chloride

Eye Irritation Rabbit Moderate  
Skin Irritation Rabbit Mild

#### 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

#### Carcinogen Status:

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

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### 12. ECOLOGICAL INFORMATION

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

**Toxicity:**

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

**POTASSIUM CHLORIDE**

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

**Persistence and Degradability:** No data available

**Bio-accumulative Potential:** No data available

**Mobility in Soil:** No data available

### 13. DISPOSAL CONSIDERATIONS

**Waste Treatment Methods:** 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 waste water 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.

### 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.

### 15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

POTASSIUM CHLORIDE

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### 15. REGULATORY INFORMATION

<b>CERCLA/SARA 313 Emission reporting</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>Inventory - United States TSCA - Sect. 8(b)</b>	Present
<b>Australia (AICS):</b>	Present
<b>Standard for the Uniform Scheduling for Drugs and Poisons:</b>	Schedule 4
<b>EU EINECS/ELINCS List</b>	231-211-8
<b>Water for injection</b>	
<b>CERCLA/SARA 313 Emission reporting</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>Inventory - United States TSCA - Sect. 8(b)</b>	Present
<b>Australia (AICS):</b>	Present
<b>REACH - Annex IV - Exemptions from the obligations of Register:</b>	Present
<b>EU EINECS/ELINCS List</b>	231-791-2
<b>Calcium chloride USP</b>	
<b>CERCLA/SARA 313 Emission reporting</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>Australia (AICS):</b>	Present
<b>EU EINECS/ELINCS List</b>	Not Listed
<b>Magnesium chloride hexahydrate</b>	
<b>CERCLA/SARA 313 Emission reporting</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>Australia (AICS):</b>	Present
<b>EU EINECS/ELINCS List</b>	Not Listed
<b>Sodium chloride</b>	
<b>CERCLA/SARA 313 Emission reporting</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>Inventory - United States TSCA - Sect. 8(b)</b>	Present
<b>Australia (AICS):</b>	Present
<b>EU EINECS/ELINCS List</b>	231-598-3

### 16. OTHER INFORMATION

#### Text of CLP/GHS Classification abbreviations mentioned in Section 3

Serious eye damage/eye irritation-Cat.2A; H319 - Causes serious eye irritation

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

**Reasons for Revision:** Updated Section 2 - Hazard Identification. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking.

**Revision date:** 14-Feb-2018

**Prepared by:** Product Stewardship Hazard Communication  
Pfizer Global Environment, Health, and Safety Operations

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Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

**End of Safety Data Sheet**