



# SAFETY DATA SHEET

Revision date 14-Jun-2025

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

### 1.1. Product identifier

**Product Name** Penicillin G potassium for injection  
**Product Code(s)** 150  
**Trade Name:** PFIZERPEN  
**Chemical Family:** Penicillin

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

**Recommended Use** Pharmaceutical product used as antibiotic agent

### 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 Ltd  
Ramsgate Road  
Sandwich, Kent  
CT13 9NJ  
United Kingdom  
+00 44 (0)1304 616161

**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

**Respiratory sensitization** Category 1  
**Skin sensitization** Category 1

#### 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



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## Signal word

Danger

## Hazard statements

H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled  
H317 - May cause an allergic skin reaction

## Precautionary Statements - EU (§28, 1272/2008)

P261 - Avoid breathing dust/fume/gas/mist/vapors/spray  
P272 - Contaminated work clothing should not be allowed out of the workplace  
P280 - Wear protective gloves/protective clothing/eye protection/face protection  
P284 - In case of inadequate ventilation wear respiratory protection  
P304 + P341 - IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing  
P342 + P311 - If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician  
P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention  
P362 + P364 - Take off contaminated clothing and wash it before reuse  
P501 - Dispose of contents/container in accordance with local, regional, national, and international regulations as applicable  
P302 + P352 - IF ON SKIN: Wash with plenty of soap and water

## 2.3. Other hazards

### Other hazards

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

## 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)
Penicillin G potassium (CAS #: 113-98-4)	*		204-038-0	Resp. Sens.1 (H334) Skin Sens.1 (H317)	Not classified	No data available	No data available
Citric acid (CAS #: 77-92-9)	**		201-069-1 (607-750-00-3)	Eye Irrit. 2A (H319)SE 3 (H335)	Not classified	No data available	No data available

#### NonHazardous

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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)
Sodium citrate (CAS #: 68-04-2)	**	-	200-675-3	Not classified	Not classified	No data available	No data available

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

Acute Toxicity Estimate No information available

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
Penicillin G potassium 113-98-4	8900	No data available	No data available	No data available	No data available
Citric acid 77-92-9	5400	>2000	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

\*\* to adjust pH

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. Non-hazardous ingredients provided for completeness.

## Section 4: FIRST AID MEASURES

### 4.1. Description of first aid measures

<b>Inhalation</b>	Remove to fresh air. Seek immediate medical attention/advice.
<b>Eye contact</b>	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
<b>Skin contact</b>	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
<b>Ingestion</b>	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** For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

### 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 or water spray.

### 5.2. Special hazards arising from the substance or mixture

**Specific hazards arising from the chemical** Fine particles (such as dust and mists) may fuel fires/explosions.

**Hazardous combustion products** Emits toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, sulfur oxides and other sulfur-containing compounds.

#### Explosion data

**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 the spill or leak. Collect spilled material by a method that controls dust generation. Avoid use of a filtered vacuum to clean spills of dry solids. Clean contaminated surface 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** Minimize dust generation and accumulation. Avoid inhalation and contact with skin, eye, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should

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## General hygiene considerations

be controlled with dust collectors, HEPA filtration systems or other equivalent controls.  
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.

#### Citric acid

Czech Republic  
Germany DFG

4 mg/m<sup>3</sup>

TWA-MAK: 2 mg/m<sup>3</sup>; I(2); inhalable fraction

Peak: 4 mg/m<sup>3</sup>; respirable fraction

Germany TRGS

TWA-AGW; 2 mg/m<sup>3</sup> (exposure factor 2); inhalable fraction

Russia

MAC: 1 mg/m<sup>3</sup>

Switzerland

TWA-MAK: 2 mg/m<sup>3</sup>; inhalable dust

STEL-KZGW: 4 mg/m<sup>3</sup>; inhalable dust

#### Pfizer Occupational Exposure Band (OEB) Statement:

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

### 8.2. Exposure controls

#### Engineering controls

Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

#### 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 gloves (e.g. Nitrile, etc.) are 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.).

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<b>Skin and body protection</b>	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (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 half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.).
<b>Thermal hazards</b>	No information available.
<b>Environmental exposure controls</b>	No information available.

## Section 9: PHYSICAL AND CHEMICAL PROPERTIES

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

<b>Appearance</b>	Crystalline powder
<b>Physical state</b>	Powder
<b>Color</b>	White
<b>Odor</b>	Odorless.
<b>Odor threshold</b>	No information available

**Property**

## Values

<u>Property</u>	<u>Value</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

### Penicillin G potassium

1.83

## 9.2. Other information

<b>Molecular formula</b>	Mixture
<b>Molecular weight</b>	Mixture

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## 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.

## 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 various forms of the active ingredient. The remaining information describes the potential hazards of the individual ingredients.

#### Short term

Individuals who are allergic to penicillin antibiotics could have allergic reaction, possibly severe (anaphylactic). If an allergic reaction occurs, the worker should be removed to the nearest emergency room and the appropriate therapy instituted.

#### Known Clinical Effects:

May cause effects similar to those seen in clinical use including transient diarrhea, nausea and abdominal pain. Individuals who are sensitive to beta lactam antibiotics, both penicillins and cephalosporins, may experience contact or systemic hypersensitivity and anaphylaxis upon exposure to this drug.

#### Acute toxicity

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.

#### Skin corrosion/irritation

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

#### Respiratory or skin sensitization

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.

#### Reproductive toxicity

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.

#### Aspiration hazard

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

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

#### Penicillin G potassium

Mouse Oral LD50 6257 mg/kg

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Rat Oral LD50 8900 mg/kg  
Rabbit Oral LD50 5848 mg/kg

## Citric acid

Mouse Oral LD50 5400 mg/kg

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Penicillin G potassium	= 8900 mg/kg ( Rat )	-	-
Citric acid	= 3 g/kg ( Rat )	> 2000 mg/kg ( Rat )	-

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

### Citric acid

Eye Irritation Rabbit Severe  
Skin Irritation Rabbit Mild

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

### Penicillin V Potassium

14 Day(s) Rat Oral 2400 mg/kg/day NOAEL None identified  
14 Day(s) Mouse Oral 2400 mg/kg/day NOAEL None identified  
13 Week(s) Rat Oral 750 mg/kg/day LOEL Gastrointestinal system  
13 Week(s) Mouse Oral 250 mg/kg/day LOEL Gastrointestinal system

## Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

### Penicillin V Potassium

*In Vitro* Bacterial Mutagenicity (Ames) Negative  
*In Vitro* Cell Transformation Assay Mouse Lymphoma Positive with activation  
Sister Chromatid Exchange Chinese Hamster Ovary (CHO) cells Positive without activation  
Sister Chromatid Exchange Chinese Hamster Ovary (CHO) cells Negative with activation

## Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

### Penicillin V Potassium

2 Year(s) Rat Oral 1000 mg/kg/day NOEL Not carcinogenic  
2 Year(s) Mouse Oral 1000 mg/kg/day NOEL Not carcinogenic

**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:**

The use and/or disposal of this material, its metabolites and degradation products is not expected to cause adverse effects upon animals, plants, humans, other organisms, or the environment.

### 12.1. Toxicity



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

### Penicillin G potassium

*Daphnia magna* (Water Flea) LC50 48 hours > 1000 mg/L

*Nitzschia fonticola* (Diatom) LC50 630 2000 mg/L

**Aquatic Toxicity Comments:** A greater than symbol (>) indicates that aquatic toxicity was not observed at the maximum dose tested.

## 12.2. Persistence and degradability

**Persistence and degradability** No information available.

## 12.3. Bioaccumulative potential

**Bioaccumulation** No information available.

### Penicillin G potassium

1.83

## 12.4. Mobility in soil

**Mobility in soil** No information available.

## 12.5. Results of PBT and vPvB assessment

**PBT and vPvB assessment** Based on available data, the classification criteria are not met.

Chemical name	PBT and vPvB assessment
Penicillin V Potassium	Not PBT/vPvB
Sodium citrate	Not PBT/vPvB PBT assessment does not apply
Citric acid	Not PBT/vPvB

## 12.6. Endocrine disrupting properties

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

## 12.7. Other adverse effects

**Other adverse effects** No information available.

**PMT or vPvM properties** 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.

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## 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.

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

## Section 15: REGULATORY INFORMATION

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

Penicillin G potassium

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	204-038-0

Sodium citrate

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	200-675-3
AICS	Present
Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)	Schedule 5

Citric acid

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	201-069-1
AICS	Present

### National regulations

#### 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

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**WPO (GSchV) SR 814.201; WPA (GSchG) SR 814.20**  
**Major Accidents Ordinance SR 814.012**

Not applicable  
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)

Chemical name	Restricted substance per REACH Annex XVII	Substance subject to authorization per REACH Annex XIV
Citric acid 77-92-9	75	-

## Persistent Organic Pollutants

Not applicable

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

Not applicable.

Chemical name	Biocidal Products Regulation (EU) No 528/2012 (BPR)
Citric acid 77-92-9	Product-type 2: Disinfectants and algicides not intended for direct application to humans or animals Product-type 6: Preservatives for products during storage

## Explosives Precursors Marketing and Use (2019/1148)

Not applicable

### Legend:

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

H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled H317 - May cause an allergic skin reaction

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**Data Sources:** Pfizer proprietary drug development information. Publicly available toxicity information.

**Reason for revision** Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information.

**Revision date** 14-Jun-2025

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

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