



SAFETY DATA SHEET

Revision date 22-Apr-2022

Version 3.11

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

1.1. Product identifier

Product Name	Bicillin L-A
Product Code(s)	00230797
Synonyms	Penicillin G benzathine injectable suspension
Trade Name:	Bicillin L-A
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
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1.3. Details of the supplier of the safety data sheet

Pfizer Inc
235 East 42nd Street
New York, New York 10017
1-800-879-3477

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

1.4. Emergency telephone number

Emergency Telephone	Chemtrec 1-800-424-9300 International Chemtrec (24 hours):+1-703-527-3887
E-mail address	pfizer-MSDS@pfizer.com

Section 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

Respiratory sensitization	Category 1
Skin sensitization	Category 1

2.2. Label elements

Signal word	Danger
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Hazard statements	H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled H317 - May cause an allergic skin reaction
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Precautionary Statements	P261 - Avoid breathing dust/fume/gas/mist/vapors/spray P272 - Contaminated work clothing must not be allowed out of the workplace P280 - Wear protective gloves/protective clothing/eye protection/face protection P304 + P341 - IF INHALED: If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing P342 + P311 - If experiencing respiratory symptoms: Call a POISON CENTRE or doctor/physician P284 - In case of inadequate ventilation wear respiratory protection P302+ P352 - IF ON SKIN: Wash with plenty of soap and water
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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 all local and national regulations



2.3. Other hazards

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 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	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Penicillin G benzathine 41372-02-5	45		Not Listed	Acute Tox. 4 (H302) Resp. Sens. Cat. 1 (H334) Skin Sens. Cat. 1 (H317)	Not Listed	No data available	No data available

NonHazardous

Chemical name	Weight-%	REACH Registration Number	EC No	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Povidone 9003-39-8	*		Not Listed	No data available	Not Listed	No data available	No data available
Carboxymethylcellulose 9000-11-7	*		Not Listed	No data available	Not Listed	No data available	No data available
Lecithin 8002-43-5	*		232-307-2	No data available	Not Listed	No data available	No data available
Methyl-p-hydroxyben	*		202-785-7	No data	Not Listed	No data	No data

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zoate 99-76-3				available		available	available
Propylparaben 94-13-3	*		202-307-7	No data available	Not Listed	No data available	No data available
Sodium Citrate Buffer MIXTURE	*		Not Listed	No data available	Not Listed	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	Dermal LD50	Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapor - mg/L	Inhalation LC50 - 4 hour - gas - ppm
Penicillin G benzathine 41372-02-5	2000	No data available	No data available	No data available	No data available
Povidone 9003-39-8	100000	No data available	No data available	No data available	No data available

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. Non-hazardous ingredients provided for completeness.

Section 4: FIRST AID MEASURES

4.1. Description of first aid measures

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

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

5.3. Advice for firefighters

Special protective equipment 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. Wipe up with a damp cloth and place in container for disposal. 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

Avoid breathing mist or aerosols. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. 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 be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

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

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8.1. Control parameters

Povidone

Russia

MAC: 10 mg/m³

Methyl-p-hydroxybenzoate

Russia

MAC: 4 mg/m³

Propylparaben

Russia

MAC: 10 mg/m³

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.

Penicillin G benzathine

Pfizer Occupational Exposure Band (OEB):

OEB 2 - Sensitizer (control exposure to the range of 100ug/m³ to < 1000ug/m³, 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. 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.

Environmental exposure controls

No information available.

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.).

Skin and body protection

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.).

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 half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.).

General hygiene considerations

Handle in accordance with good industrial hygiene and safety practice.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical state

Aqueous suspension

Color

White

Odor

No information available.

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Odor threshold	No information available
Molecular formula	Mixture
Molecular weight	Mixture

<u>Property</u>	<u>Values</u>
pH	No data available
Melting point / freezing point	No data available
Boiling point / boiling range	
Flash point	No information available
Evaporation rate	No data available
Flammability (solid, gas)	No data available
Flammability Limit in Air	
Upper flammability limit:	No data available
Lower flammability limit:	No data available
Vapor pressure	No data available
Vapor density	No data available
Relative density	No data available
Water solubility	No data available
Solubility(ies)	No data available
Partition coefficient	No data available
Autoignition temperature	No data available
Decomposition temperature	No data available
Kinematic viscosity	No data available
Dynamic viscosity	No data available
Particle characteristics	
Particle Size	No information available
Particle Size Distribution	No information available
Explosive properties	No information available

9.2. Other information

No information available

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 data available.

10.2. Chemical stability

Stability Stable under normal conditions.

Explosion data

Sensitivity to Mechanical Impact No data available.

Sensitivity to Static Discharge No data 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.

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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 the individual ingredients. The information included in this section describes the potential hazards of various forms of the active ingredient.

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: (Species, Route, End Point, Dose)

Penicillin G benzathine

Mouse Oral LD50 2 g/kg

Povidone

Rat Oral LD50 100 g/kg

Lecithin

Rat Oral LD50 > 8 ml/kg

Methyl-p-hydroxybenzoate

Mouse Oral LD50 > 8 g/kg

Rat Oral LD 50 2100 mg/kg

Propylparaben

Mouse Oral LD 50 6332 mg/kg

Mouse Sub-tenon injection (eye) LD 50 200 mg/kg

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Povidone	= 100 g/kg (Rat)	-	-

Acute Toxicity Comments:

A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

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

Methyl-p-hydroxybenzoate

Skin irritation Rabbit Non-irritating

Eye irritation Rabbit Slight

Skin Sensitization Guinea Pig Negative

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

Methyl-p-hydroxybenzoate

28 Day(s) Rat Oral 250 mg/kg/day NOAEL Gastrointestinal System, Spleen, Thymus

Propylparaben

3 Week(s) Rat Oral 27.1 g/kg LOAEL Endocrine system

4 Week(s) Rat Oral 347.2 mg/kg LOAEL Male reproductive system

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

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Methyl-p-hydroxybenzoate

Embryo / Fetal Development Rabbit Oral 300 mg/kg/day NOEL Maternal toxicity, Developmental toxicity

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

Methyl-p-hydroxybenzoate

In Vivo Dominant Lethal Assay Rat Negative

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. See below

Povidone

IARC

Group 3 (Not Classifiable)

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Endocrine disrupting properties No information available.

11.2.2. Other information

Other adverse effects No information available.

Section 12: ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been investigated. Releases to the environment should be avoided.

12.1. Toxicity

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

Methyl-p-hydroxybenzoate

Oryzias latipes (Japanese Rice Fish) OECD LC50 96 hours 59.5 mg/L

Daphnia magna (Water Flea) ISO EC50 48 hours 11.2 mg/L

12.2. Persistence and degradability

Persistence and degradability

Biodegradation: (Method, Inoculum, Biodeg Study, Result, Endpoint, Duration, Classification)

Methyl-p-hydroxybenzoate

OECD Activated sludge Ultimate (CO2 Evolution) 89 % After 28 Day(s) Ready

12.3. Bioaccumulative potential

Bioaccumulation

No information available.

12.4. Mobility in soil

Mobility in soil No information available.

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12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment No information available.

Chemical name	PBT and vPvB assessment
Methyl-p-hydroxybenzoate	The substance is not PBT / vPvB
Propylparaben	The substance is not PBT / vPvB

12.6. Endocrine disrupting properties

Endocrine disrupting properties No information available.

12.7. Other adverse effects

No information available.

Section 13: DISPOSAL CONSIDERATIONS

13.1. 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 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.

Section 15: REGULATORY INFORMATION

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

Penicillin G benzathine

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
EINECS	Not Listed

Povidone

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

Carboxymethylcellulose

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

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Lecithin

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	232-307-2
AICS	Present

Methyl-p-hydroxybenzoate

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	202-785-7
AICS	Present

Propylparaben

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	202-307-7
AICS	Present

Sodium Citrate Buffer

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
EINECS	Not Listed

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 (EC) 1005/2009

Not applicable

Chemical name	Plant protection products directive (91/414/EEC)
Lecithin - 8002-43-5	Plant protection agent

Legend:

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

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

AICS - Australian Inventory of Chemical Substances

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 H-Statements referred to under section 3

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Sensitization, skin-Cat.1; H317 - May cause an allergic skin reaction Sensitization, respiratory-Cat.1; H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed

Data Sources: Safety data sheets for individual ingredients. 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 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information.

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Prepared By Pfizer Global Environment, Health, and Safety

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