



# SAFETY DATA SHEET

Revision date 21-Feb-2026

Version 3.01

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

### 1.1. Product identifier

**Product Name** Azithromycin for Injection (Hospira, Inc)

**Product Code(s)** PZ03061

**Trade Name:** Not applicable

**Chemical Family:** Mixture

### 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

Hospira, A Pfizer Company  
 275 North Field Drive  
 Lake Forest, Illinois 60045  
 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: Regulated according to Regulation (EC) 1272/2008 and/or other applicable regulations.

**Hazardous to the aquatic environment - acute** Category 1 - (H400)

**Hazardous to the aquatic environment - chronic** Category 1 - (H410)

### 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** Warning  
**Hazard statements** H410 - Very toxic to aquatic life with long lasting effects

**Precautionary Statements - EU (§28, 1272/2008)** P273 - Avoid release to the environment  
P391 - Collect spillage  
P501 - Dispose of contents/container in accordance with local, regional, national, and international regulations as applicable

## 2.3. Other hazards

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

**Azithromycin dihydrate**  
Pfizer OEL TWA-8 Hr: 500 µg/m<sup>3</sup>

**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. (Index No.)	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Azithromycin dihydrate (CAS #: 117772-70-0)	50		Not Listed	Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)	Not classified	100	10
Citric acid (CAS #: 77-92-9)	5-<10		201-069-1 (607-750-00-3)	Eye Irrit. 2A (H319)SE 3 (H335)	Not classified	No data available	No data available

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Sodium hydroxide (CAS #: 1310-73-2)	**	-	215-185-5 (011-002-00-6)	Skin Corr.1A (H314)	Eye Irrit. 2 :: 0.5%<=C<2% Skin Corr. 1A :: C>=5% Skin Corr. 1B :: 2%<=C<5% Skin Irrit. 2 :: 0.5%<=C<2%	No data available	No data available
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## 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
Azithromycin dihydrate 117772-70-0	> 2000	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
Sodium hydroxide 1310-73-2	325	1350	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

\*\* 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.

## **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, and nitrogen oxides.

#### 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. Do not breathe dust. Avoid contact with skin, eyes or 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

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**General hygiene considerations** 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.

#### **Azithromycin dihydrate**

Pfizer OEL TWA-8 Hr: 500 µg/m<sup>3</sup>

#### **Citric acid**

Czech Republic	4 mg/m <sup>3</sup>
Germany DFG	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> (2I); 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

#### **Sodium hydroxide**

ACGIH OEL (Ceiling)	2 mg/m <sup>3</sup>
ACGIH TLV	Ceiling: 2 mg/m <sup>3</sup>
Austria	TWA-TMW: 2 mg/m <sup>3</sup> ; inhalable fraction STEL-KZGW: 4 mg/m <sup>3</sup> (8 X 5 min); inhalable fraction
Bulgaria	TWA: 2.0 mg/m <sup>3</sup> ; alkaline aerosols
Czech Republic	1 mg/m <sup>3</sup> Ceiling: 2 mg/m <sup>3</sup>
Denmark	Ceiling: 2 mg/m <sup>3</sup> ;
Estonia	TWA: 1 mg/m <sup>3</sup> ; STEL: 2 mg/m <sup>3</sup> ;
Finland	Ceiling: 2 mg/m <sup>3</sup> ;
France	2 mg/m <sup>3</sup>
Hungary	TWA-AK: 1 mg/m <sup>3</sup> ; STEL-CK: 2 mg/m <sup>3</sup> ;
Ireland	STEL: 2 mg/m <sup>3</sup> ;
Ceiling Limit Value	2 mg/m <sup>3</sup>
Latvia	TWA: 0.5 mg/m <sup>3</sup> ;
Poland	TWA-NDS: 0.5 mg/m <sup>3</sup> ; STEL-NDSch: 1 mg/m <sup>3</sup> ;
Romania	TWA: 1 mg/m <sup>3</sup> ;
Slovakia	STEL: 3 mg/m <sup>3</sup> ;
Spain	TWA: 2 mg/m <sup>3</sup> ;
Switzerland	STEL (VLA-EC): 2 mg/m <sup>3</sup> ; TWA-MAK: 2 mg/m <sup>3</sup> ; inhalable dust STEL-KZGW: 2 mg/m <sup>3</sup> ; inhalable dust
OSHA PEL	TWA: 2 mg/m <sup>3</sup>
United Kingdom	(vacated) Ceiling: 2 mg/m <sup>3</sup> STEL: 2 mg/m <sup>3</sup> ;

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## 8.2. Exposure controls

<b>Engineering controls</b>	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.
<b>Personal protective equipment</b>	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.
<b>Eye/face protection</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>Hand protection</b>	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.).
<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>	Fluffy powder, lyophilized
<b>Physical state</b>	Powder
<b>Color</b>	White
<b>Odor</b>	Odorless.
<b>Odor threshold</b>	No information available

#### Property

<b>Melting point / freezing point</b>	<u>Values</u> No data available
<b>Boiling point or initial boiling point and boiling range</b>	No data available
<b>Flammability (solid, gas)</b>	No data available
<b>Lower and upper explosion limit/flammability limit</b>	
Lower explosion limit	No data available
Upper explosion limit	No data available
<b>Flash point</b>	No data available

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<b>Autoignition temperature</b>	No data available
<b>Decomposition temperature</b>	
<b>SADT (°C)</b>	No data available
<b>pH</b>	6.4 - 6.8
<b>pH (as aqueous solution)</b>	No data available
<b>Kinematic viscosity</b>	No data available
<b>Dynamic viscosity</b>	No data available
<b>Solubility</b>	Highly soluble: Water
<b>Vapor pressure</b>	No data available
<b>Density and/or relative density</b>	No data available
<b>Bulk density</b>	No data available
<b>Liquid Density</b>	No data available
<b>Vapor density</b>	No data available
<b>Particle characteristics</b>	
<b>Particle Size</b>	No information available
<b>Particle Size Distribution</b>	No information available

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

**Azithromycin dihydrate**  
Measured 7 Log P 0.67

## **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.

**Hazardous polymerization** Will not occur.

### **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**

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<b>General Information:</b>	The information included in this section describes the potential hazards of the individual ingredients
<b>Short term</b>	May cause irritation (based on animal data). Individuals sensitive to this chemical or other materials in its chemical class may develop allergic reactions.
<b>Known Clinical Effects:</b>	May cause effects similar to those seen in clinical use including transient diarrhea, nausea and abdominal pain. Based on clinical trials in humans, possible adverse effects following exposure to this compound may include: diarrhea, nausea, abdominal pain, irregular heartbeat (cardiac arrhythmia), liver effects, allergic reaction.
<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)**

### **Azithromycin dihydrate**

Mouse (F) Oral LD50 4000 mg/kg  
Mouse (M) Oral LD50 3000 mg/kg  
Rat Oral LD50 > 2000 mg/kg

### **Citric acid**

Mouse Oral LD50 5400 mg/kg

### **Sodium hydroxide**

Mouse IP LD50 40 mg/kg

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Citric acid	= 3 g/kg ( Rat )	> 2000 mg/kg ( Rat )	-
Sodium hydroxide	= 325 mg/kg ( Rat )	= 1350 mg/kg ( Rabbit )	-

**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)**

### **Azithromycin dihydrate**

Antigenicity- Active anaphylaxis Guinea Pig Negative  
Antigenicity- Passive cutaneous anaphylaxis Rabbit Negative  
Antigenicity- Passive cutaneous anaphylaxis Mouse Negative

### **Citric acid**

Eye Irritation Rabbit Severe  
Skin Irritation Rabbit Mild

### **Sodium hydroxide**

Eye Irritation Rabbit Severe  
Skin Irritation Rabbit Severe

**Irritation / Sensitization Comments:** Azithromycin may be slightly irritating to eyes, based on extrapolation of minimal and moderate irritation seen in intravenous and intramuscular irritation studies, respectively.

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

### **Azithromycin dihydrate**

1 Month(s) Rat Oral 50 mg/kg/day LOAEL Liver

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1 Month(s) Dog Oral 25 mg/kg/day LOAEL Liver  
6 Month(s) Rat Oral 40 mg/kg/day LOAEL Liver  
6 Month(s) Dog Oral 10 mg/kg/day LOAEL Liver  
1 Month(s) Rat Intravenous 5 mg/kg/day NOAEL Liver  
1 Month(s) Dog Intravenous 5 mg/kg/day NOAEL Liver

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

### **Azithromycin dihydrate**

Reproductive & Fertility Rat Oral 10 mg/kg/day NOEL Fertility  
Peri-/Postnatal Development Rat Oral 40 mg/kg/day NOEL Not Teratogenic  
Embryo / Fetal Development Mouse Oral 200 mg/kg/day NOEL Fetotoxicity, Maternal Toxicity  
Embryo / Fetal Development Rat Oral 40 mg/kg/day NOEL Fetotoxicity, Maternal Toxicity  
Embryo / Fetal Development Rabbit Oral 10 mg/kg/day LOAEL Maternal Toxicity  
Embryo / Fetal Development Rabbit Oral 40 mg/kg/day NOEL Fetotoxicity, Not Teratogenic

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

### **Azithromycin dihydrate**

Bacterial Mutagenicity (Ames) *Salmonella* Negative  
*In Vivo* Cytogenetics Mouse Lymphoma Negative  
*In Vitro* Cytogenetics Mouse Negative  
*In Vitro* Cytogenetics Human Lymphocytes Negative

**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:** Releases to the environment should be avoided. In the environment, this substance is expected to mainly reside in the aquatic environment and slowly degrade. Classification is based on mixture calculation methods based on component data.

### **12.1. Toxicity**

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

##### **Azithromycin dihydrate**

*Daphnia magna* (Water Flea) OECD EC50 48 hours 120 mg/L  
*Hyallela azteca* (Freshwater Amphipod) OECD LC50 96 hours > 120 mg/L  
*Oncorhynchus mykiss* (Rainbow Trout) OECD LC50 96 hours > 84 mg/L  
Green Algae OECD EC50 72 Hours 0.0037 mg/L  
*Microcystis aeruginosa* (Blue-green Alga) OECD ErC50 96 hours 0.0018 mg/L

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

#### **Bacterial Inhibition: (Inoculum, Method, End Point, Result)**

##### **Azithromycin dihydrate**

*Aspergillus niger* (Fungus) OECD MIC > 1000 mg/L  
*Trichoderma viride* (Fungus) OECD MIC > 1000 mg/L  
*Clostridium perfringens* (Bacterium) OECD MIC 2.0 mg/L  
*Bacillus subtilis* (Bacterium) OECD MIC 2.0 mg/L

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

### Azithromycin dihydrate

*Eisenia foetida* (Earthworm) TAD NOEC 28 Days 1000 mg/kg

## Chronic Aquatic Toxicity: (Species, Method, Duration, Endpoint, Result, Adverse Endpoint)

### Azithromycin dihydrate

*Pimephales promelas* (Fathead Minnow) OECD 32 Day(s) NOEC 4.6 mg/L Survival

*Ceriodaphnia dubia* (Daphnids) OPPTS 7 Day(s) NOEC 0.0044 mg/L Reproduction

## 12.2. Persistence and degradability

**Persistence and degradability** No information available.

## 12.3. Bioaccumulative potential

### **Bioaccumulation**

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

#### Azithromycin dihydrate

Measured 7 Log P 0.67

## 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
Citric acid	Not PBT/vPvB
Sodium hydroxide	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.

## 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.

This material is regulated for transportation as a hazardous material/dangerous good.

**14.1 UN number:** UN 3077  
**14.2 UN proper shipping name:** Environmentally Hazardous Substance, Solid, n.o.s (Azithromycin dihydrate)  
**14.3 Transport hazard class(es):** 9  
**14.4 Packing group:** III  
**14.5 Environmental Hazard(s):** Marine Pollutant

### 5 kg/5L Exception:

UN3082 and UN3077 materials contained in good quality packaging in the quantities listed below are not subject to the dangerous goods transportation regulations by any mode:

\* Single packagings containing a net quantity of 5 liters or less for liquids or a net mass of 5 kg or less for solids.

\* Combination packagings containing a net quantity per inner packaging of 5 liters or less for liquids or a net mass of 5 kg or less for solids.

## Section 15: REGULATORY INFORMATION

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

Azithromycin dihydrate	
<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>EINECS</b>	Not Listed
Citric acid	
<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present
<b>EINECS</b>	201-069-1
<b>AICS</b>	Present
Sodium hydroxide	
<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>Hazardous Substances RQs</b>	1000 lb
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present
<b>EINECS</b>	215-185-5
<b>AICS</b>	Present
<b>Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)</b>	Schedule 5 Schedule 6

### National regulations

#### Germany

**Chemical Prohibition Ordinance (ChemVerbotsV)**

Not applicable

TRGS 905

Not applicable

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## 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)

Chemical name	Restricted substance per REACH Annex XVII	Substance subject to authorization per REACH Annex XIV
Citric acid 77-92-9	75	-
Sodium hydroxide 1310-73-2	75	-

## **Persistent Organic Pollutants**

Not applicable

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

Not applicable.

## **Biocidal Products Regulation (EU) No 528/2012 (BPR)**

Chemical name	Biocidal Products Regulation (EU) No 528/2012 (BPR)
Citric acid 77-92-9	Product-type 2: Disinfectants and algacides 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/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

# SAFETY DATA SHEET

Product Name Azithromycin for Injection (Hospira, Inc)  
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## 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. H314 - Causes severe skin burns and eye damage. H335 - May cause respiratory irritation  
H400 - Very toxic to aquatic life. H410 - Very toxic to aquatic life with long lasting effects.

**Data Sources:** Safety data sheets for individual ingredients. Publicly available toxicity information.

**Reason for revision** Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 16 - Other Information.

**Revision date** 21-Feb-2026

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

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