



# SAFETY DATA SHEET

Revision date 16-Sep-2021

Version 1

Page 1 / 11

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

### 1.1. Product identifier

<b>Product Name</b>	Daptomycin for Injection (rapid reconstitution)
<b>Product Code(s)</b>	PF00262
<b>Trade Name:</b>	Not applicable
<b>Chemical Family:</b>	Not determined

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

<b>Recommended Use</b>	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

Hospira UK Limited  
 Horizon  
 Honey Lane  
 Hurley  
 Maidenhead, SL6 6RJ  
 United Kingdom

### 1.4. Emergency telephone number

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

## Section 2: HAZARDS IDENTIFICATION

### 2.1. Classification of the substance or mixture

GHS - Classification

<b>Specific target organ toxicity (repeated exposure)</b>	Category 2 - (H373)
---	---------------------

### 2.2. Label elements

<b>Signal word</b>	Warning
<b>Hazard statements</b>	H373 - May cause damage to organs through prolonged or repeated exposure
<b>Precautionary Statements</b>	P260 - Do not breathe dust/fume/gas/mist/vapors/spray P314 - Get medical attention/advice if you feel unwell

# SAFETY DATA SHEET

Product Name Daptomycin for Injection (rapid reconstitution)  
Revision date 16-Sep-2021

Page 2 / 11  
Version 1

P501 - Dispose of contents/container in accordance with all local and national regulations



## 2.3. Other hazards

### Note:

An Occupational Exposure Value has been established for this substance ( see Section 8 ).

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)
Daptomycin 103060-53-3	5 - 10		Not Listed	STOT RE 2 (H373)	Not Listed	No data available	No data available
Sodium hydroxide 1310-73-2	**		215-185-5	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
Citric acid 77-92-9	< 1		201-069-1	Eye Irrit. 2A (H319)	Not Listed	No data available	No data available

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

#### Acute Toxicity Estimate

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
Sodium hydroxide 1310-73-2	325	1350	No data available	No data available	No data available
Citric acid	3000	2000	No data available	No data available	No data available

# SAFETY DATA SHEET

Product Name Daptomycin for Injection (rapid reconstitution)  
Revision date 16-Sep-2021

Page 3 / 11  
Version 1

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
77-92-9					

## Additional information

\*\* to adjust pH

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

## 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.

## Section 5: FIRE-FIGHTING MEASURES

### 5.1. Extinguishing media

**Suitable Extinguishing Media** Use carbon dioxide, dry chemical, 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.

### 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

# SAFETY DATA SHEET

Product Name Daptomycin for Injection (rapid reconstitution)  
Revision date 16-Sep-2021

Page 4 / 11  
Version 1

**For emergency responders** Section 8). Minimize exposure.  
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 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**

Minimize dust generation and accumulation. Avoid breathing dust. Avoid contact with eyes, skin 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 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**

### 8.1. Control parameters

#### **Exposure Limits**

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

#### **Daptomycin**

Pfizer OEL TWA-8 Hr: 300 µg/m<sup>3</sup>

#### **Sodium hydroxide**

ACGIH OEL (Ceiling)	2 mg/m <sup>3</sup>
ACGIH TLV	Ceiling: 2 mg/m <sup>3</sup>
Austria	2 mg/m <sup>3</sup>
	STEL 4 mg/m <sup>3</sup>
Bulgaria	2.0 mg/m <sup>3</sup>
Czech Republic	1 mg/m <sup>3</sup>
	Ceiling: 2 mg/m <sup>3</sup>
Denmark	Ceiling: 2 mg/m <sup>3</sup>
Estonia	1 mg/m <sup>3</sup>
	STEL: 2 mg/m <sup>3</sup>

# SAFETY DATA SHEET

Product Name Daptomycin for Injection (rapid reconstitution)  
Revision date 16-Sep-2021

Page 5 / 11  
Version 1

Finland	Ceiling: 2 mg/m <sup>3</sup>
France	2 mg/m <sup>3</sup>
Hungary	1 mg/m <sup>3</sup>
	STEL: 2 mg/m <sup>3</sup>
Ireland	STEL: 2 mg/m <sup>3</sup>
Ceiling Limit Value	2 mg/m <sup>3</sup>
Latvia	0.5 mg/m <sup>3</sup>
Poland	STEL: 1 mg/m <sup>3</sup>
	0.5 mg/m <sup>3</sup>
Romania	1 mg/m <sup>3</sup>
	STEL: 3 mg/m <sup>3</sup>
Slovakia	2 mg/m <sup>3</sup>
Spain	STEL: 2 mg/m <sup>3</sup>
Switzerland	2 mg/m <sup>3</sup>
	STEL: 2 mg/m <sup>3</sup>
OSHA PEL	2 mg/m <sup>3</sup>
	(vacated) Ceiling: 2 mg/m <sup>3</sup>
United Kingdom	STEL: 2 mg/m <sup>3</sup>
<b>Citric acid</b>	
Czech Republic	4 mg/m <sup>3</sup>
Germany	2 mg/m <sup>3</sup>
	Ceiling / Peak: 4 mg/m <sup>3</sup>
Germany	2 mg/m <sup>3</sup>
Russia	MAC: 1 mg/m <sup>3</sup>
Switzerland	2 mg/m <sup>3</sup>
	STEL: 4 mg/m <sup>3</sup>

## 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.).

# SAFETY DATA SHEET

Product Name Daptomycin for Injection (rapid reconstitution)  
Revision date 16-Sep-2021

Page 6 / 11  
Version 1

**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	Lyophilized powder
Color	Light yellow to Light brown
Odor	No information available.
Odor threshold	No information available
Molecular formula	Mixture
Molecular weight	Mixture

#### Property

#### Values

pH	4.5-5.0
Melting point / freezing point	215
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	Highly soluble:
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.

# SAFETY DATA SHEET

Product Name Daptomycin for Injection (rapid reconstitution)  
Revision date 16-Sep-2021

Page 7 / 11  
Version 1

## 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

**Short term** Accidental ingestion may cause effects similar to those seen in clinical use.  
**Known Clinical Effects:** Adverse effects associated with therapeutic use include headache, allergic skin rash, liver effects, effects on musculoskeletal system, muscle pain, muscle weakness, neuromuscular effects. Ingestion of this material may cause effects similar to those generally seen in clinical use of antibiotics including gastrointestinal irritation, vomiting, transient diarrhea, nausea, and abdominal pain.

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

#### Daptomycin

Rat Oral Minimum Lethal Dose > 2000 mg/kg  
Rat Dermal Minimum Lethal Dose > 200 mg/kg  
Mouse IV Minimum Lethal Dose > 700 mg/kg  
Rat IV Minimum Lethal Dose > 140 mg/kg

#### Sodium hydroxide

Mouse IP LD50 40 mg/kg

#### Citric acid

Rat Oral LD50 3000 mg/kg

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

#### Daptomycin

Skin irritation Rabbit Slight  
Eye irritation Rabbit Slight

#### Sodium hydroxide

Eye Irritation Rabbit Severe  
Skin Irritation Rabbit Severe

#### Citric acid

Eye Irritation Rabbit Severe  
Skin Irritation Rabbit Mild

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

#### Daptomycin

1 Month(s) Rat Intravenous 10 mg/kg/day LOAEL Skeletal muscle, Kidney

# SAFETY DATA SHEET

Product Name Daptomycin for Injection (rapid reconstitution)  
Revision date 16-Sep-2021

Page 8 / 11  
Version 1

3 Month(s) Rat Intravenous 1 mg/kg/day LOAEL Skeletal muscle, Kidney  
6 Month(s) Rat Intravenous 2 mg/kg/day LOAEL Kidney, Skeletal muscle, Bone Marrow  
1 Month(s) Dog Intravenous 10 mg/kg/day LOAEL Bone Marrow, Skeletal muscle, Peripheral nervous system  
3 Month(s) Dog Intravenous 1 mg/kg/day NOAEL Skeletal muscle  
6 Month(s) Dog Intravenous 2 mg/kg/day NOAEL Skeletal muscle, Peripheral nervous system  
1 Month(s) Monkey Intravenous 10 mg/kg/day NOAEL None identified

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

### **Daptomycin**

Reproductive & Fertility Rat Intravenous 150 mg/kg/day NOAEL Negative: Fertility, Fetotoxicity  
Embryo / Fetal Development Rat Intravenous 75 mg/kg/day NOAEL Negative, Not Teratogenic  
Embryo / Fetal Development Rabbit Intravenous 75 mg/kg/day NOAEL Negative, Not Teratogenic  
Peri-/Postnatal Development Rat Intravenous 75 mg/kg/day NOAEL Negative: Fetotoxicity

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

### **Daptomycin**

Bacterial Mutagenicity (Ames) *Salmonella* , *E. coli* Negative  
Mammalian Cell Mutagenicity Not specified Negative  
Chromosome Aberration Chinese Hamster Ovary (CHO) cells Negative  
*In Vivo* Micronucleus Mouse Negative  
*In Vivo* Sister Chromatid Exchange Hamster 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** No information available.

### **11.2.2. Other information**

**Other adverse effects** No information available.

## **Section 12: ECOLOGICAL INFORMATION**

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

### **12.1. Toxicity**

**No information available**

### **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.



# SAFETY DATA SHEET

Product Name Daptomycin for Injection (rapid reconstitution)  
Revision date 16-Sep-2021

Page 9 / 11  
Version 1

## 12.5. Results of PBT and vPvB assessment

### PBT and vPvB assessment

Chemical name	PBT and vPvB assessment
Sodium hydroxide	The substance is not PBT / vPvB PBT assessment does not apply
Citric acid	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

Daptomycin

<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>EINECS</b>	Not Listed
<b>Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)</b>	Schedule 4

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

# SAFETY DATA SHEET

Product Name Daptomycin for Injection (rapid reconstitution)  
Revision date 16-Sep-2021

Page 10 / 11  
Version 1

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

## 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 contains one or more substance(s) 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
Sodium hydroxide - 1310-73-2	Use restricted. See item 75.	

## Persistent Organic Pollutants

Not applicable

## Ozone-depleting substances (ODS) regulation (EC) 1005/2009

Not applicable

## EU - Biocides

Chemical name	EU - Biocides
Citric acid - 77-92-9	Product-type 1: Human hygiene

## 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

Skin corrosion/irritation-Cat.1A; H314 - Causes severe skin burns and eye damage. Specific target organ toxicity, repeated exposure-Cat.2; H373 - May cause damage to organs through prolonged or repeated exposure. Serious eye damage/eye irritation-Cat.2A; H319 - Causes serious eye irritation.

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

**Reason for revision** New data sheet.

**Revision date** 16-Sep-2021

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

# SAFETY DATA SHEET

Product Name Daptomycin for Injection (rapid reconstitution)  
Revision date 16-Sep-2021

Page 11 / 11  
Version 1

---

**Pfizer Inc believes that the information contained in this 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.**