



# SAFETY DATA SHEET

Revision date: 27-May-2015

Version: 2.0

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

### Product Identifier

**Material Name:** Synercid IV Injection

**Trade Name:** SYNERCID  
**Chemical Family:** Not determined

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

**Intended Use:** Pharmaceutical product used as antibiotic agent

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

Pfizer Inc  
Pfizer Pharmaceuticals Group  
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## 2. HAZARDS IDENTIFICATION

### Classification of the Substance or Mixture

**GHS - Classification** Not classified as hazardous

### US OSHA Specific - Classification

**Physical Hazard:** Combustible Dust

### EU Classification:

EU Indication of danger: Not classified

### Label Elements

**Hazard Statements:** May form combustible dust concentrations in air

### Other Hazards

No data available

### Australian Hazard Classification (NOHSC):

Non-Hazardous Substance. Non-Dangerous Goods.

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

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### 3. COMPOSITION / INFORMATION ON INGREDIENTS

#### Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Quinupristin	120138-50-3	Not Listed	Not Listed	Not Listed	30
Dalfopristin	112362-50-2	Not Listed	Not Listed	Not Listed	70

**Additional Information:** Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

### 4. FIRST AID MEASURES

#### Description of First Aid Measures

- Eye Contact:** Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
- 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.
- Inhalation:** Remove to fresh air and keep patient at rest. Seek medical attention immediately.

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

- Symptoms and Effects of Exposure:** For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.
- Medical Conditions Aggravated by Exposure:** None known

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

**Notes to Physician:** None

### 5. FIRE FIGHTING MEASURES

**Extinguishing Media:** Extinguish fires with CO<sub>2</sub>, extinguishing powder, foam, or water.

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

- Hazardous Combustion Products:** Formation of toxic gases is possible during heating or fire. May include oxides of carbon nitrogen sulfur
- Fire / Explosion Hazards:** Dust can form an explosive mixture in air. Fine particles (such as dust and mists) may fuel fires/explosions.

#### Advice for Fire-Fighters

During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

### 6. ACCIDENTAL RELEASE MEASURES

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

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

#### Environmental Precautions

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

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### Methods and Material for Containment and Cleaning Up

**Measures for Cleaning / Collecting:** Remove all sources of ignition. Contain the source of the spill if it is safe to do so. 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.

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

## 7. HANDLING AND STORAGE

### Precautions for 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 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.

### Conditions for Safe Storage, Including any Incompatibilities

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

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

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

### Control Parameters

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.

### Quinupristin

**Pfizer Occupational Exposure Band (OEB):** OEB 3 (control exposure to the range of 10ug/m<sup>3</sup> to < 100ug/m<sup>3</sup>)

### Dalfopristin

**Pfizer Occupational Exposure Band (OEB):** OEB 2 (control exposure to the range of 100ug/m<sup>3</sup> to < 1000ug/m<sup>3</sup>)

### 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).

**Hands:** Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

**Eyes:** Wear safety glasses or goggles if eye contact is possible.

**Skin:** Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

**Respiratory protection:** If airborne exposures are within or exceed the Occupational Exposure Band (OEB) range, wear an appropriate respirator with a protection factor sufficient to control exposures to the bottom of the OEB range.

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### 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Physical State:</b>	Powder	<b>Color:</b>	White to slightly yellow
<b>Odor:</b>	No data available.	<b>Odor Threshold:</b>	No data available.
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture

<b>Solvent Solubility:</b>	No data available
<b>Water Solubility:</b>	Soluble
<b>pH:</b>	4.3-5.0 (10% aqueous solution)
<b>Melting/Freezing Point (°C):</b>	No data available
<b>Boiling Point (°C):</b>	No data available.

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

##### Dalfopristin

Predicted Log P -1.33

##### Quinupristin

Predicted Log P -1.33

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

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

#### Flammability:

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

### 10. STABILITY AND REACTIVITY

<b>Reactivity:</b>	No data available
<b>Chemical Stability:</b>	Stable under normal conditions of use.
<b>Possibility of Hazardous Reactions</b>	
<b>Oxidizing Properties:</b>	None
<b>Conditions to Avoid:</b>	Fine particles (such as dust and mists) may fuel fires/explosions.
<b>Incompatible Materials:</b>	As a precautionary measure, keep away from strong oxidizers
<b>Hazardous Decomposition Products:</b>	No data available

### 11. TOXICOLOGICAL INFORMATION

#### Information on Toxicological Effects

**Short Term:** May cause eye irritation May cause skin irritation. May produce allergic reactions after systemic administration.

**Known Clinical Effects:** May cause effects similar to those generally seen in clinical use of antibiotics including gastrointestinal irritation, vomiting, transient diarrhea, nausea, and abdominal pain.

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

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### 11. TOXICOLOGICAL INFORMATION

#### Dalfopristin

1 Month(s) Rat Intravenous 10 mg/kg/day NOEL None identified  
1 Month(s) Monkey No route specified 25 mg/kg/day NOEL No effects at maximum dose

#### Quinupristin

1 Month(s) Rat No route specified 1 mg/kg/day NOEL None identified  
1 Month(s) Monkey No route specified 16 mg/kg/day NOEL No effects at maximum dose

#### Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

##### Dalfopristin

Fertility and Embryonic Development Rat No route specified 120 mg/kg/day NOEL No effects at maximum dose  
Fertility and Embryonic Development Mouse No route specified 40 mg/kg/day No effects at maximum dose  
Fertility and Embryonic Development Rabbit No route specified 12 mg/kg/day NOEL No effects at maximum dose

##### Quinupristin

Fertility and Embryonic Development Rat No route specified 120 mg/kg/day NOEL No effects at maximum dose  
Fertility and Embryonic Development Mouse No route specified 40 mg/kg/day NOEL No effects at maximum dose  
Fertility and Embryonic Development Rabbit No route specified 12 mg/kg/day NOEL No effects at maximum dose

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

##### Dalfopristin

Bacterial Mutagenicity (Ames) Bacteria Negative  
HGPRT Forward Gene Mutation Assay Chinese Hamster Ovary (CHO) cells Negative  
Unscheduled DNA Synthesis Rat Hepatocyte Negative  
Chromosome Aberration Chinese Hamster Ovary (CHO) cells Positive  
Micronucleus Mouse Bone Marrow Negative

##### Quinupristin

Bacterial Mutagenicity (Ames) Bacteria Negative  
HGPRT Forward Gene Mutation Assay Chinese Hamster Ovary (CHO) cells Negative  
Unscheduled DNA Synthesis Rat Hepatocyte Negative  
Chromosome Aberration Chinese Hamster Ovary (CHO) cells Negative  
Micronucleus Mouse Bone Marrow Negative

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

### 12. ECOLOGICAL INFORMATION

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

**Toxicity:** No data available

**Persistence and Degradability:** No data available

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

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

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### Dalfopristin

Predicted Log P -1.33

### Quinupristin

Predicted Log P -1.33

**Mobility in Soil:** No data available

## 13. DISPOSAL CONSIDERATIONS

**Waste Treatment Methods:** Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

## 14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

## 15. REGULATORY INFORMATION

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

#### Canada - WHMIS: Classifications

##### **WHMIS hazard class:**

Non-controlled

This product has been classified in accordance with the hazard criteria of the CPR and the SDS contains all of the information required by the CPR.

### Quinupristin

<b>CERCLA/SARA 313 Emission reporting</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>Standard for the Uniform Scheduling for Drugs and Poisons:</b>	Schedule 4
<b>EU EINECS/ELINCS List</b>	Not Listed

### Dalfopristin

<b>CERCLA/SARA 313 Emission reporting</b>	Not Listed
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### 15. REGULATORY INFORMATION

California Proposition 65	Not Listed
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
EU EINECS/ELINCS List	Not Listed

### 16. OTHER INFORMATION

<b>Data Sources:</b>	The data contained in this SDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature.
<b>Reasons for Revision:</b>	Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 7 - Handling and Storage. Updated Section 11 - Toxicology Information. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 16 - Other Information.
<b>Revision date:</b>	27-May-2015 Product Stewardship Hazard Communication
<b>Prepared by:</b>	Pfizer Global Environment, Health, and Safety Operations

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

**End of Safety Data Sheet**