

Material Name: SYNERCID® I.V. INJECTION MSDS ID: 00230636

* * *Section 1 - PRODUCT AND COMPANY IDENTIFICATION* * *

Material Name: SYNERCID® I.V. INJECTION

Manufacturer Information

KING PHARMACEUTICALS, INC. Phone: (800) 776-3637

501 Fifth Street

Bristol, TN 37620

Synonyms

SYNERCID(R) or RP 59500; QUINUPRISTIN or RP 57669; DALFOPRISTIN or RP 54476; NDC #: 61570-260-10 (500 mg SDV)

* * *Section 2 - HAZARDS IDENTIFICATION* * *

EMERGENCY OVERVIEW

Color: off-white to yellow, pale

Change in Color: hygroscopic

Physical Form: powder

Physical Hazards: Dust/air mixtures may ignite or explode.

POTENTIAL HEALTH EFFECTS

Inhalation

Short Term: allergic reactions

Long Term: no information is available

Skin

Short Term: irritation, itching, rash

Long Term: no information is available

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Eye

Short Term: irritation

Long Term: irritation

Ingestion

Short Term: nausea, vomiting, diarrhea, blood disorders, joint pain

Long Term: no information is available

* * *Section 3 - COMPOSITION / INFORMATION ON INGREDIENTS* * *

CAS	Component	Percent
112362-50-2	DALFOPRISTIN	70
120138-50-3	QUINUPRISTIN	30

* * *Section 4 - FIRST AID MEASURES* * *

Inhalation

If adverse effects occur, remove to uncontaminated area. Give artificial respiration if not breathing. Get immediate medical attention.

Skin

Wash skin with soap and water for at least 15 minutes while removing contaminated clothing and shoes. Get medical attention, if needed. Thoroughly clean and dry contaminated clothing and shoes before reuse.

Eyes

Flush eyes with plenty of water for at least 15 minutes. Then get immediate medical attention.

Ingestion

If a large amount is swallowed, get medical attention.

* * *Section 5 - FIRE FIGHTING MEASURES* * *

See Section 9 for Flammability Properties

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NFPA Ratings: Health: 1 Fire: 1 Reactivity: 0

Hazard Scale: 0 = Minimal 1 = Slight 2 = Moderate 3 = Serious 4 = Severe

Flammable Properties

Slight fire hazard. Dust/air mixtures may ignite or explode.

Extinguishing Media

carbon dioxide, regular dry chemical, regular foam, water

Fire Fighting Measures

Move container from fire area if it can be done without risk. Avoid inhalation of material or combustion by-products. Stay upwind and keep out of low areas.

Thermal Decomposition Products

Combustion: oxides of carbon, oxides of nitrogen, oxides of sulfur, phosgene

* * *Section 6 - ACCIDENTAL RELEASE MEASURES* * *

Occupational spill/release

Collect spilled material in appropriate container for disposal. Keep out of water supplies and sewers.

* * *Section 7 - HANDLING AND STORAGE* * *

Handling Procedures

Wash thoroughly after handling. Use methods to minimize dust.

Storage Procedures

Store and handle in accordance with all current regulations and standards. Refrigerate. Store between 2 C and 8 C. Avoid contact with water or moisture. Avoid contact with light. Protect from physical damage. See original container for storage recommendations. Keep separated from incompatible substances.

* * *Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION* * *

Component Exposure Limits

ACGIH, EU and OSHA have not developed exposure limits for any of this product's components.

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Ventilation

Ventilation equipment should be explosion-resistant if explosive concentrations of material are present. Provide local exhaust ventilation system. Ensure compliance with applicable exposure limits.

PERSONAL PROTECTIVE EQUIPMENT

Eyes/Face

Wear splash resistant safety goggles. Provide an emergency eye wash fountain and quick drench shower in the immediate work area.

Protective Clothing

Wear appropriate chemical resistant clothing.

Glove Recommendations

Wear appropriate chemical resistant gloves.

Protective Materials

latex

Respiratory Protection

Under conditions of frequent use or heavy exposure, respiratory protection may be needed.

Respiratory protection is ranked in order from minimum to maximum.

Consider warning properties before use.

Any air-purifying half-mask respirator equipped with organic vapor cartridge(s) in combination with an N95, R95, or P95 filter. The following filters may also be used: N99, R99, P99, N100, R100 or P100.

Any air-purifying full-facepiece respirator (gas mask) with a chin-style, front-mounted or back-mounted organic vapor canister having an N100, R100, or P100 filter.

Any powered, air-purifying respirator with a tight-fitting facepiece, organic vapor cartridge(s) and high-efficiency particulate filter(s).

Any supplied-air respirator with a full facepiece that is operated in a pressure-demand or other positive-pressure mode.

For Unknown Concentrations or Immediately Dangerous to Life or Health -

Any supplied-air respirator with a full facepiece that is operated in a pressure-demand or other positive-pressure mode in combination with an auxiliary self-contained breathing apparatus operated in pressure-demand or other positive-pressure mode.

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Any self-contained breathing apparatus that has a full facepiece and is operated in a pressure-demand or other positive-pressure mode.

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* * *Section 9 - PHYSICAL AND CHEMICAL PROPERTIES* * *

Physical State:	Solid	Appearance:	Not available		
Change in color:	hygroscopic	Color:	off-white to yellow, pale		
Physical Form:	powder	Odor:	Not Available		
Odor Threshold:	Not available	pH:	4.3 - 5.0		
pH (solution):	10 %	Melting Point:	Not available		
Boiling Point:	Not applicable	Vapor Pressure:	Not applicable		
Vapor Density (air = 1):	Not applicable	Density:	Not available		
Specific Gravity (water = 1):	Not available	Water Solubility:	soluble		
Coeff. Water/Oil Dist:	Not available				

* * *Section 10 - STABILITY AND REACTIVITY* * *

Chemical Stability

Stable at normal temperatures and pressure.

Conditions to Avoid

Avoid heat, flames, sparks and other sources of ignition. Avoid contact with incompatible materials.

Materials to Avoid

oxidizing materials

Combustion: oxides of carbon, oxides of nitrogen, oxides of sulfur, phosgene

Possibility of Hazardous Reactions

Will not polymerize.

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* * *Section 11 - TOXICOLOGICAL INFORMATION* * *

Immediate Effects

Component Analysis - LD50/LC50

The components of this material have been reviewed in various sources and no selected endpoints have been identified.

Component Carcinogenicity

None of this product's components are listed by ACGIH, IARC, or DFG.

Additional Data

Interactions with drugs may occur. Interactions with drugs may occur. This drug is normally administered intravenously. The toxicity and health effects are presumed to be essentially the same as the intravenous route of administration.

* * *Section 12 - ECOLOGICAL INFORMATION* * *

Component Analysis - Aquatic Toxicity

No LOLI ecotoxicity data are available for this product's components.

* * *Section 13 - DISPOSAL CONSIDERATIONS* * *

Disposal Methods

Dispose in accordance with all applicable regulations.

Component Waste Numbers

The U.S. EPA has not published waste numbers for this product's components.

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* * *Section 14 - TRANSPORT INFORMATION* * *

US DOT Information

No Classification assigned.

* * *Section 15 - REGULATORY INFORMATION* * *

U.S. Federal Regulations

None of this products components are listed under SARA Section 302 (40 CFR 355 Appendix A), SARA Section 311/312 (40 CFR 370.21), SARA Section 313 (40 CFR 372.65), CERCLA (40 CFR 302.4), TSCA 12(b), or require an OSHA process safety plan.

SARA 311/312

Acute Health: No Chronic Health: No Fire: No Pressure: No Reactive: No

U.S. State Regulations

None of this product's components are listed on the state lists from CA, MA, MN, NJ, PA, or RI.

Not regulated under California Proposition 65

Component Analysis - Inventory

Component	CAS	US	CA	EU	AU	PH	JP	KR	CN	NZ
DALFOPRISTIN	112362-50-2	No								
QUINUPRISTIN	120138-50-3	No								

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* * *Section 16 - OTHER INFORMATION* * *

Key / Legend

ACGIH - American Conference of Governmental Industrial Hygienists; ADR - European Road Transport; AU -Australia; BOD - Biochemical Oxygen Demand; C - Celsius; CA - Canada; CAS - Chemical Abstracts Service; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CN - China; CPR -Controlled Products Regulations; DFG - Deutsche Forschungsgemeinschaft; DOT - Department of Transportation; DSL - Domestic Substances List; EEC - European Economic Community; EINECS - European Inventory of Existing Commercial Chemical Substances; EPA - Environmental Protection Agency; EU - European Union; F - Fahrenheit; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; ICAO - International Civil Aviation Organization; IDL - Ingredient Disclosure List; IDLH - Immediately Dangerous to Life and Health; IMDG - International Maritime Dangerous Goods; JP - Japan; Kow - Octanol/water partition coefficient; KR - Korea; LEL - Lower Explosive Limit; LOLI - List Of LIsts™ - ChemADVISOR's Regulatory Database; MAK - Maximum Concentration Value in the Workplace; MEL - Maximum Exposure Limits; NFPA - National Fire Protection Agency; NIOSH - National Institute for Occupational Safety and Health; NJTSR -New Jersey Trade Secret Registry; NTP - National Toxicology Program; NZ - New Zealand; OSHA - Occupational Safety and Health Administration; PH - Philippines; RCRA - Resource Conservation and Recovery Act; RID -European Rail Transport; RTECS - Registry of Toxic Effects of Chemical Substances®; SARA - Superfund Amendments and Reauthorization Act; STEL - Short-term Exposure Limit; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act; TWA - Time Weighted Average; UEL - Upper Explosive Limit; US -**United States**

Other Information

This material safety data sheet is offered solely for your information, consideration, and investigation. King Pharmaceuticals provides no warranties, either expressed or implied, and assumes no responsibility for the accuracy of the data contained herein.

End of Sheet 00230636