

# MSDS: Capastat® Sulfate (Capreomycin for Injection, USP)

**Manufacturer:** Akorn Incorporated  
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## Section 1 - IDENTIFICATION

**TRADE NAME:** Capreomycin Sulfate for Injection, USP  
**Description:** Capreomycin Sulfate, which is to be used concomitantly with other appropriate antituberculosis agents, is indicated in pulmonary infections caused by capreomycin-susceptible strains of *M. tuberculosis*.

<b>Composition</b>	<b>CAS#</b>	<b>TLV (mg/m<sup>3</sup>)</b>	<b>PEL (mg/m<sup>3</sup>)</b>	<b>Content</b>
Capreomycin Sulfate	1405-37-4	Not Established	Not Established	1g
Water for Injection	7732-18-5	Not Established	Not Established	QS

**Inactives:** None

**Common name of active ingredient:** Capreomycin Sulfate  
**Chemical Formula (s):** C<sub>25</sub>H<sub>46</sub>N<sub>14</sub>O<sub>11</sub>S  
**Legal Category:** Prescription Only

## Section 2 - HAZARDOUS INGREDIENTS

**Routes of Entry:** Inhalation and skin contact  
**Effects of Overexposure:** Kidney effects and hearing impairment with dizziness and tinnitus (ringing of the ear) have been reported with therapeutic administration of capreomycin by injection. If swallowed capreomycin is not absorbed in significant quantities.  
**Medical Conditions Aggravated by Exposure:** Hypersensitivity to capreomycin  
**Carcinogenicity:** Not considered carcinogenic, not listed by IARC, ACGIH, NTP, or OSHA

## Section 3 - PHYSICAL AND CHEMICAL CHARACTERISTICS

<b>Appearance:</b>	White to off-white lyophilized plug	<b>Odor:</b>	Odorless
<b>Physical State:</b>	Solid	<b>Vapor Density (g/m<sup>3</sup>):</b>	Not Established
<b>Boiling Point (C°):</b>	Not Established	<b>Specific Gravity:</b>	Not Established
<b>Vapor Pressure (mmHg at 20°C):</b>	Not Established	<b>Latex Free:</b>	Yes
<b>Viscosity:</b>	Not Established		
<b>pH:</b>	4.5 to 7.5 in a 30mg/mL solution		
<b>Solubility in Water:</b>	Very Soluble		



**Section 7 - HEALTH HAZARDS**

Nephrotoxicity following parenteral administration of Capreomycin Sulfate is notable. The elderly patient, patients with abnormal renal function or dehydration, and patients receiving other nephrotoxic drugs are at much greater risk for developing acute tubular necrosis.

Damage to the auditory and vestibular divisions of cranial nerve VIII has been associated with Capreomycin Sulfate given to patients with abnormal renal function or dehydration and in those receiving medications with additive auditory toxicities. These patients often experience dizziness, tinnitus, vertigo, and loss of high-tone acuity.

Neuromuscular blockage or respiratory paralysis may occur following rapid intravenous infusion. If capreomycin is ingested, toxicity would be unlikely because it is poorly absorbed (less than 1 %) from an intact gastrointestinal system.

Hypokalemia, hypocalcemia, hypomagnesemia, and an electrolyte disturbance resembling Bartter's syndrome have been reported to occur in patients with capreomycin toxicity.

**Section 8 - PROTECTION INFORMATION**

<b>Respiratory Protection:</b>	Use an approved respirator
<b>Eye Protection:</b>	Chemical goggles and/or face shield
<b>Ventilation:</b>	Laboratory fume hood or local exhaust ventilation
<b>Other Protective Equipment:</b>	Chemical-resistant gloves and body covering to minimize skin contact. If handled in a ventilated enclosure, as in a laboratory setting, respirator may not be required. Safety glasses are always required.

**Section 9 - HANDLING AND STORAGE**

<b>Handling:</b>	No special protective equipment or procedures are required in the clinical or home environment.
<b>Storage:</b>	Store at controlled room temperature 15° to 30°C (59° to 86° F) prior to reconstitution. <b>KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN</b>

**Section 10 - ACCIDENTAL RELEASE MEASURES**

<b>Spills:</b>	Wear protective equipment, including eye protection, to avoid exposure
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<b>Section 11 - TOXICOLOGY INFORMATION</b>
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**Acute Exposure**

**Oral:** Capreomycin sulfate - Rat, 6000 mg/kg, no deaths  
**Skin:** The subcutaneous median lethal dose in mice was 514 mg/kg.  
**Inhalation:** No applicable information found.  
**Eye Contact:** Capreomycin sulfate (1% solution) - Rabbit, nonirritant

**Chronic Exposure**

**Target Organ Effects:** Two-year studies in rats (subcutaneously given up to 250mg/kg/day) and dogs (intramuscularly given 25 or 50mg/kg/day or 100 mg/kg 3 times/week) reported kidney effects. Hearing loss was also reported in dogs with prolonged exposure. In addition to renal and cranial nerve VIII toxicity demonstrated in animal toxicology studies, cataracts developed in 2 dogs on doses of 62mg/kg and 100mg/kg for prolonged periods.

**Reproduction:** Fertility and reproduction were not adversely affected in rats or rabbits given subcutaneous injections. In teratology studies, a low incidence of “wavy ribs” was noted in litters of female rats treated with daily doses of 50mg/kg or more of capreomycin.

**Sensitization:** Guinea pig, intravenous, negative systemic response

**Mutagenicity:** No applicable information found

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<b>Section 12 - ECOLOGICAL INFORMATION</b>
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**Ecotoxicity Data:**

Rainbow trout, 96-hour median lethal concentration:	>62.4 mg/L
Daphnia magna, 48-hour median effective concentration:	49.4 mg/L
Green algae ( <i>S. capricornutum</i> ), 72-hour median effective concentration:	0.16 mg/L
Activated sludge respiration inhibition, 3-hour median effective concentration:	>84.4 mg/L

**Environmental Fate:**

Log $K_{ow}$ :	< -5 (pH 7)
Bioconcentration factor (calculated):	0.003
Dissociation constants:	6.4, 8.1, 10.2, 11.6

**Environmental Summary:**

Capreomycin sulfate is highly toxic to green algae, but is no more than moderately toxic to aquatic invertebrates, fish, and activated sludge microorganisms. Measurable concentrations of capreomycin sulfate in the atmosphere are not expected since it is a non-volatile solid. The solubility of capreomycin in water is very high. An aqueous capreomycin sulfate concentration in activated municipal sewage sludge declined from 4.2 mg/L to less than 0.8 mg/L after 8 hours. The environmental fate process contributing to the rapid decline of its aqueous concentration could not be determined. Since sorption of the compound to the sludge solids could not be ruled out, the possibility exists that the compound did not biodegrade during the 8-hour decline. According to the relationship between  $K_{ow}$  and the bioconcentration factor, it is not expected to bioconcentrate in aquatic organisms.

**Aquatic Exposure Guideline (AEG):**

AEG for Drinking Water:	500 micrograms/L
AEG for Chronic Exposure of Aquatic Organisms:	25 micrograms/L
AEG for Acute Exposure of Aquatic Organisms:	160 micrograms/L

**Section 13 - REGULATORY INFORMATION**

U.S. Regulations		Capreomycin sulfate
TSCA	-	Not listed
CERCLA	-	Not listed
SARA 302	-	Not listed
SARA 313	-	Not listed
OSHA Substance Specific -		Not listed
<b>EC Classification</b>		Not assigned an overall EC classification

**Section 14 - DISPOSAL INFORMATION**

Dispose of material according to Federal, State, and Local regulations. The method typically used is incineration.

**Section 15 - TRANSPORTATION INFORMATION**

**DOT:** Not classified as hazardous by Department of Transportation regulations. This product does not pose an unreasonable risk to health and safety or property when transported in commerce.

**ICAO/IATA:** Not Regulated

**Section 16 - OTHER INFORMATION**

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