

# Slildenafil Citrate Injection USP

## Safety Data Sheet

### SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1. Product identifier

Product name : Slildenafil Citrate Injection USP -- NDC 55150-166-13 (10mg/12.5mL 1s)

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

Use of the substance/mixture : Pharmaceutical

#### 1.3. Details of the supplier of the safety data sheet

AuroMedics  
6 Wheelling Road  
Dayton, NJ 08810  
T 609-642-1136

#### 1.4. Emergency telephone number

Emergency number : 888-238-7880, option 2

### SECTION 2: Hazards identification

#### 2.1. Classification of the substance or mixture

##### Classification (GHS-US)

Not classified

#### 2.2. Label elements

##### GHS-US labeling

No labeling applicable

#### 2.3. Other hazards

No additional information available

#### 2.4. Unknown acute toxicity (GHS-US)

Not applicable

### SECTION 3: Composition/information on ingredients

#### 3.1. Substance

Not applicable

#### 3.2. Mixture

Name	Product identifier	%	Classification (GHS-US)
Sildenafil citrate	(CAS No) 171599-83-0	0.1124	Skin Irrit. 2, H315 Eye Irrit. 2A, H319 STOT SE 3, H335

Full text of H-phrases: see section 16

### SECTION 4: First aid measures

#### 4.1. Description of first aid measures

- First-aid measures after inhalation : Move to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen and monitor closely. Get medical attention immediately.
- First-aid measures after skin contact : Immediately flush with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Get medical attention. Wash contaminated clothing before reuse.
- First-aid measures after eye contact : Immediately flush with plenty of water for at least 15 minutes occasionally lifting upper and lower eyelids. If easy to do, remove contact lenses. Get medical attention if symptoms persist.
- First-aid measures after ingestion : DO NOT induce vomiting. If victim is fully conscious, give a cupful of water. Never give anything by mouth to an unconscious person. If vomiting occurs, keep head lower than the hips to help prevent aspiration. Call a physician or poison control center immediately.

#### 4.2. Most important symptoms and effects, both acute and delayed

- Symptoms/injuries after inhalation : Dust may irritation respiratory system.
- Symptoms/injuries after skin contact : May cause cause irritation.
- Symptoms/injuries after eye contact : May cause eye irritation on direct contact.

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Symptoms/injuries after ingestion : Ingestion may cause irritation and malaise. May cause serious or fatal hypersensitivity (anaphylactic) reactions in some individuals.

### 4.3. Indication of any immediate medical attention and special treatment needed

No additional information available

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

Suitable extinguishing media : Use extinguishing media appropriate for surrounding fire.

### 5.2. Special hazards arising from the substance or mixture

Fire hazard : None known.

### 5.3. Advice for firefighters

Protection during firefighting : Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

General measures : No special measures required.

#### 6.1.1. For non-emergency personnel

No additional information available

#### 6.1.2. For emergency responders

No additional information available

### 6.2. Environmental precautions

Prevent entry to sewers and public waters.

### 6.3. Methods and material for containment and cleaning up

For containment : Stop the flow of material, if this is without risk.

Methods for cleaning up : Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid dust formation.

### 6.4. Reference to other sections

No additional information available

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

Precautions for safe handling : Wear protective clothing as described in Section 8 of this safety data sheet. Do not breathe dust. Avoid contact with eyes, skin, and clothing. Do not taste or swallow. Use only with adequate ventilation. Wash thoroughly after handling. Minimize dust generation and accumulation.

### 7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store at controlled room temperature at 20–25 °C (68–77°F). Store away from incompatible materials

### 7.3. Specific end use(s)

No additional information available

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

Sildenafil citrate (171599-83-0)	
ACGIH	Not applicable
OSHA	Not applicable

### 8.2. Exposure controls

Appropriate engineering controls : Local exhaust and general ventilation must be adequate to meet exposure standards.

Hand protection : Wear protective gloves.

Eye protection : Wear safety glasses with side shields (or goggles).

Skin and body protection : Wear suitable working clothes.

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Respiratory protection : If engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (in countries where exposure limits have not been established), an approved respirator must be worn. In the United States of America, if respirators are used, a program should be instituted to assure compliance with OSHA 29 CFR 1910.134. Respirator type: Use high efficiency particulate respirator with appropriate filter.

### SECTION 9: Physical and chemical properties

#### 9.1. Information on basic physical and chemical properties

Physical state : Solid  
Appearance : Powder.  
Color : White  
Odor : Odorless.  
Odor threshold : No data available  
pH : No data available  
Melting point : No data available  
Freezing point : No data available  
Boiling point : No data available  
Flash point : No data available  
Relative evaporation rate (butyl acetate=1) : No data available  
Flammability (solid, gas) : No data available  
Explosion limits : No data available  
Explosive properties : No data available  
Oxidizing properties : No data available  
Vapor pressure : No data available  
Relative density : No data available  
Relative vapor density at 20 °C : No data available  
Solubility : No data available  
Log Pow : No data available  
Log Kow : No data available  
Auto-ignition temperature : No data available  
Decomposition temperature : No data available  
Viscosity : No data available  
Viscosity, kinematic : No data available  
Viscosity, dynamic : No data available

#### 9.2. Other information

No additional information available

### SECTION 10: Stability and reactivity

#### 10.1. Reactivity

No additional information available

#### 10.2. Chemical stability

The product is stable at normal handling and storage conditions.

#### 10.3. Possibility of hazardous reactions

Will not occur.

#### 10.4. Conditions to avoid

Heat. Water, moisture. Minimize dust generation and accumulation.

#### 10.5. Incompatible materials

Not determined

#### 10.6. Hazardous decomposition products

Not determined

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### SECTION 11: Toxicological information

#### 11.1. Information on toxicological effects

Acute toxicity	: Not classified
Skin corrosion/irritation	: Not classified
Serious eye damage/irritation	: Not classified
Respiratory or skin sensitization	: Not classified
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified
Reproductive toxicity	: Not classified
Specific target organ toxicity (single exposure)	: Not classified
Specific target organ toxicity (repeated exposure)	: Not classified
Aspiration hazard	: Not classified

### SECTION 12: Ecological information

#### 12.1. Toxicity

No additional information available

#### 12.2. Persistence and degradability

No additional information available

#### 12.3. Bioaccumulative potential

No additional information available

#### 12.4. Mobility in soil

No additional information available

#### 12.5. Other adverse effects

Effect on the global warming : No known ecological damage caused by this product.

### SECTION 13: Disposal considerations

#### 13.1. Waste treatment methods

Waste disposal recommendations : Dispose of contents/container in accordance with local/regional/national/international regulations.

### SECTION 14: Transport information

#### Department of Transportation (DOT)

In accordance with DOT

Not a dangerous good as defined in transport regulations

### SECTION 15: Regulatory information

#### 15.1. US Federal regulations

No additional information available

#### 15.2. US State regulations

No additional information available

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### SECTION 16: Other information

Full text of H-phrases::

Eye Irrit. 2A	Serious eye damage/eye irritation Category 2A
Skin Irrit. 2	Skin corrosion/irritation Category 2
STOT SE 3	Specific target organ toxicity (single exposure) Category 3
H315	Causes skin irritation
H319	Causes serious eye irritation
H335	May cause respiratory irritation

*This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product*