

*SAFETY DATA SHEET***Cisatracurium Besylate Injection USP 2.0 mg/mL (PRESERVED)****1. Product and Company Information**

Product Identifier: Cisatracurium Besylate Injection USP 2.0 mg/mL  
Synonyms: None  
National Drug Code: 2.0 mg/mL - 70069- 161-01 (10 mL),  
Recommended Use: Intravenous Injection  
Company: Somerset Therapeutics LLC  
Somerset, NJ 08873  
Contact Telephone: 1800-417-9175  
E-Mail:  
Emergency Phone Number:

**2. Hazardous(s) Identification**

Physical Hazards: Not classifiable  
Health Hazards: Not classifiable.  
Symbol(s): None.  
Signal Word: None.  
Hazard Statement(s): None.  
Precautionary Statement(s): None.  
Hazards Not Otherwise Classified: None  
Supplementary Information: Based on available data, not classified as hazardous according to the criteria of the Globally Harmonized System

**3. Composition and Information on Ingredients**

<b>Chemical Name</b>	<b>CAS Number</b>
Cisatracurium Besylate	96946-42-8
Benzenesulfonic Acid	98-11-3
Benzyl Alcohol	100-51-6
Water for Injection USP	7732-18-5

The exact percentage (concentration) of the composition is being withheld as a trade secret is required.

#### 4. First Aid Measures

- Eye Contact** In case of contact, immediately flush eyes with plenty of water for at least 15 minutes and get medical attention if irritation persists.
- Skin Contact:** Remove contaminated clothing and launder before reuse. Wash with soap and water. Get medical attention if irritation persists.
- Inhalation:** If inhaled, remove to fresh air. If not breathing give artificial respiration, preferably mouth-to-mouth. If breathing is difficult give oxygen. Get medical attention.
- Ingestion:** Rinse mouth with water many times. Never give fluids or induce vomiting if the victim is unconscious or having convulsions. Get immediate medical attention.

#### 5. Fire-Fighting Measures

- Extinguishing Media:** Use extinguishing agent suitable for type of surrounding fire
- Hazardous Combustion Products:** Not determined
- Fire Fighting Procedures:** As in any fire, wear self-contained breathing apparatus and full protective gear
- Fire / Explosion Hazards:** Not determined

#### 6. Accidental Release Measures

- Health and Safety Precautions:** For personal protection see section 8.
- Measures for Cleaning / Collecting:** Recover product and place in an appropriate container for disposal.
- Measures for Environmental Protections:** Contain material and prevent release to waterways or soil.

#### 7. Handling and Storage:

- Handling:** Handle in accordance with good industrial hygiene and safety practice.
- Storage:** Store according to label instructions.

## 8. Exposure Controls / Personal Protection

**Exposure Limits** No special provisions are required under normal product use conditions. When handling bulk formulation, use in a well-ventilated area.

**Hands:** Gloves not required during normal product use conditions. Wear impervious gloves when handling the bulk formulation.

**Eyes:** Eye protection not needed during typical product use conditions. Wear eye protection as appropriate when handling the bulk formulation.

**Respiratory protection:** Respiratory protection is not needed during normal product use. When handling the bulk formulation, an approved respirator (i.e. NIOSH, EN, etc.) should be worn when exposures are expected to exceed the applicable limits.

**Other PPE Data:** Wear appropriate body coverings if contact may occur.

## 9. Physical and Chemical Properties

**Appearance :** Clear colorless to slightly yellow or greenish yellow solution

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

**Evaporation Rate (Gram/s):** No data available

**Vapour Pressure (kPa):** No data available

**Vapour Density (g/ml):** No data available

**Specific Gravity:** 0.9505 to 1.0505 g/mL

**Viscosity:** No data available

**Flammability:** Not flammable

**Flash Point (Liquid) (°C):** Not flammable

**Upper Explosive Limits (Liquid) (% by Vol.):** No data available

**Lower Explosive Limits (Liquid) (% by Vol.):** No data available

## 10. Stability and Reactivity

**Reactivity:** No data available

**Chemical Stability:** Stable under normal conditions

**Incompatible Materials:** No data available

**Hazardous Decomposition Products** No data available

**Hazardous Polymerization** No data available

## 11. Toxicological Information

### Routes of Exposure:

**Oral:** Yes

**Dermal:** Yes

**Inhalation:** Unlikely

**Acute Toxicity - Oral:** Data for component (s) given below.

Chemical Name	Acute Test	Value	Units	Species
Cisatracurium Besylate (CAS: 96946-42-8)	LD50 =	50 < LD50 < 500	mg/kg, for a similar material	Rats

## 12. Ecological Information

### 12.1. Toxicity

Data for component (s) given below.

Chemical Name	Percent	48h EC50 (daphnia-mg/l) (48HLCD)	Species	Duration
Cisatracurium Besylate (CAS: 96946-42-8)	0.1-1	14	Daphnia magna	48 Hours

Chemical Name	Percent	72h IC50 (algae - mg/l) (72HICA)	Species	Duration
Cisatracurium Besylate (CAS: 96946-42-8)	0.1-1	>4000	Activated sludge	72 Hours

### 12.3. Bioaccumulative potential

Not determined

### 12.4. Mobility in soil

Not determined.

### 12.5. Results of PBT or vPvB assessment

Chemical safety report is not required for this substance/product.

### 12.6. Other adverse effects

Do not allow undiluted material or large quantities to reach groundwater, bodies of water or sewer system.

#### Notes:

- EC50:** Concentration in water that produces 50% mortality in *Daphnia* sp.
- LC50:** Concentration in water that produces 50% mortality in fish.
- EbC50/ErC50:** Concentration in water that produces 50% inhibition of growth and in algae.

## 13. Disposal Conditions

Disposal should be made in accordance with country, federal, state and local regulations.

#### **14. Transportation Information**

**ADR, DOT, ICAO/IATA, IMDG/IMO**

**Status:** Not regulated

**14.1. UN Number:** Not applicable

**14.2. Proper shipping name:** Not applicable

**14.3. Hazard class:** Not applicable

**14.4. Packing group:** Not applicable

**14.5. Environmental hazard:** Not applicable

**14.6. Special Provisions:** Not applicable

**14.7. Transport in bulk: according to Annex II of MARPOL 73/78 and the IBC**

**Code:**

#### **15. Regulatory Information**

**DOT Designations:** Non-hazardous

**RCRA Hazardous Waste:** Not Listed

**FDA Designations:** Prescription only medication.

NDC No. 2.0 mg/mL - 70069- 161-01 (10 mL),

#### **16. Other Information**

**NFPA Rating:**

Health: 1

Flammability: 0

Reactivity: 0

**Revision Date:** 08/10/2019

**Revision Number:** 01

**Disclaimer:** As of the date of issuance, we are providing available information relevant to the handling of this material. All information contained herein is offered with the good faith belief that it is accurate. In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.