

*SAFETY DATA SHEET***Cisatracurium Besylate Injection USP 2.0 mg/mL & 10 mg/mL****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- 141-01 (5 mL),
10.0 mg/mL - 70069-151-01 (20 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

Chemical Name	CAS Number
Cisatracurium Besylate	96946-42-8
Benzenesulfonic Acid	98-11-3
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- 141-01 (5 mL),

10.0 mg/mL - 70069-151-01 (20 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.