

## **SECTION 1: IDENTIFICATION**

### **1.1. Identification**

Product Name : Cisatracurium Besylate Injection  
Other means of identification : Cisatracurium Besylate Injection

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

Use of the substance/mixture : Pharmaceutical

### **1.3. Supplier Details**

Caplin Steriles Limited, Survey No. 895 & 897, Guruvarajakandigai, Sirupuzhalpettai (Post), Gummidipoondi (Taluk), Thiruvallur (District), Pin Code: 601 201, Tamil Nadu (State), INDIA.

### **1.4. Emergency Telephone Number**

Number : +91-4467901901/02/03

## **SECTION 2: HAZARDS IDENTIFICATION**

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

GHS-US Classification : 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 (CAS No.)	%
Cisatracurium Besylate	96946-42-8	0.1 - 1
Benzyl Alcohol (Multi-dose vials only)	100-51-6	0.1 - 1
Benzenesulfonic Acid	98-11-3	< 1

## **SECTION 4: FIRST AID MEASURES**

### **4.1. Description of first-aid measures**

After Inhalation : Remove from source of exposure. If signs of toxicity occur, seek medical attention.

Provide symptomatic/supportive care as necessary.

After Skin Contact : Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

After Eye Contact : Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

After Ingestion : Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

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

After Inhalation : None anticipated under normal product handling conditions.

After Skin Contact : None anticipated under normal product handling conditions.

After Eye Contact : May cause eye irritation.

After Ingestion : May be harmful if swallowed.

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

No additional information available.

### **SECTION 5: FIRE FIGHTING MEASURES**

#### **5.1. Extinguishing media**

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

Unsuitable extinguishing media : None.

#### **5.2. Specific hazards arising from the substance or mixture**

Fire Hazard : Non Known

#### **5.3. Advice for firefighters**

Protection during firefighting : Firefighters should wear full protective gear

### **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 materials for containment and cleaning up**

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

## **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 : Do not eat, drink or smoke when using this product.

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

Storage Conditions : Refrigerate at 2° to 8°C (36° to 46°F)

## **SECTION 8: EXPOSURE CONTROLS AND PERSONAL PROTECTION**

### **8.1. Control parameters**

#### **Cisatracurium Besylate (96946-42-8)**

Not applicable

#### **Benzyl Alcohol (100-51-6) (Multiple-dose Vials only)**

AIHA	WEEL TWA (ppm)	10 ppm
------	----------------	--------

#### **Benzenesulfonic Acid (98-11-3)**

Not applicable

### **8.2. Exposure controls**

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

Hand protection : Use suitable gloves to minimize skin contact.

Eye protection : Use protective goggles.

Skin and body protection : Wear suitable working clothes.

Respiratory protection : If airborne concentrations are above the applicable exposure limits, use NIOSH approved respiratory protection.

## **SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**

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

Physical State : Liquid

Appearance	: Clear
Color	: Colorless to slightly yellow or greenish-yellow
Odor	: Odorless
Odor Threshold	: No data available
pH	: 3.0 – 3.8
Melting Point	: No data available
Boiling Point	: No data available
Flash Point	: No data available
Freezing Point	: No data available
Flammability (solid, gas)	: No data available
Vapour Pressure	: No data available
Relative Vapor Density at 20°C	: No data available
Relative Density	: No data available
Solubility	: Completely soluble
Partition Coefficient: n-octanol/water	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity Kinematic	: No data available
Viscosity dynamic	: No data available
Explosion limits	: No data available
Explosive properties	: No data available
Oxidizing properties	: No data 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**

Air contact.

### **10.5. Incompatible materials**

None Known

### **10.6. Hazardous decomposition products**

Not determined.

## SECTION 11: TOXICOLOGICAL INFORMATION

### 11.1. Information on toxicological effects

Acute toxicity : Not Classified.

#### Cisatracurium Besylate (96946-42-8)

ATE US (oral)	100 mg/kg body weight
---------------	-----------------------

#### Benzyl Alcohol (100-51-6) (Multiple-dose Vials only)

LD50 oral rat	1230 mg/kg
LD50 dermal rabbit	2 g/kg
LC50 inhalation rat (mg/l)	8.8 mg/l/4h
ATE US (oral)	1230 mg/kg
ATE US (dermal)	2000 mg/kg

#### Benzenesulfonic Acid (98-11-3)

LD50 oral rat	1100 mg/kg
ATE US (oral)	1100 mg/kg body weight

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
STOT-single exposure	: Not classified
STOT-repeated exposure	: Not classified
Aspiration hazard	: Not classified

## SECTION 12: ECOLOGICAL INFORMATION

### 12.1. Toxicity

#### Benzyl Alcohol (100-51-6)

LC50 fish 1	460 mg/l (Exposure time: 96 h - Species: Pimephales promelas [static])
EC50 Daphnia 1	23 mg/l (Exposure time: 48 h - Species: water flea)
LC50 fish 2	10 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static])

### 12.2. Persistence and degradability

No additional information available

### **12.3. Bioaccumulative potential**

#### **Benzyl Alcohol (100-51-6) (Multiple-dose Vials only)**

Partition coefficient n-octanol/water (Log Pow)	1.1
---	-----

### **12.4. Mobility in soil**

No additional information available

### **12.5. Other adverse effects**

No additional information available

## **SECTION 13: DISPOSAL CONSIDERATIONS**

### **13.1. Waste treatment methods**

Product/Packaging 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 applicable

## **SECTION 15: REGULATORY INFORMATION**

### **15.1. US Federal Regulations**

#### **Benzyl Alcohol (100-51-6) (Multiple-dose Vials only)**

Listed on the United States TSCA (Toxic Substances Control Act) inventory

#### **Benzenesulfonic Acid (98-11-3)**

Listed on the United States TSCA (Toxic Substances Control Act) inventory

### **15.2. US State Regulations**

#### **Benzyl Alcohol (100-51-6) (Multiple-dose Vials only)**

U.S. - Massachusetts - Right To Know List

U.S. - Minnesota - Hazardous Substance List

U.S. - Pennsylvania - RTK (Right to Know) List

#### **Benzenesulfonic Acid (98-11-3)**

U.S. - New Jersey - Right to Know Hazardous Substance List

## **SECTION 16: OTHER INFORMATION**

None

**History:**

**Issued Date** : 11.11.22  
**Revision Date** : Nil  
**Version** : 00

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.

**----End of SDS---**