



# SAFETY DATA SHEET

Revision date 06-Dec-2021

Version 4.01

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## Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

### 1.1. Product identifier

**Product Name** Cisatracurium Besylate Solution for Injection  
**Product Code(s)** PZ02293  
**Trade Name:** Cisatracurium Besylate  
**Chemical Family:** Not determined

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

**Recommended Use** Pharmaceutical product

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

Pfizer Inc  
235 East 42nd Street  
New York, New York 10017  
1-800-879-3477

Pfizer Ireland Pharmaceuticals  
OSG Building  
Ringaskiddy, Co. Cork.  
Ireland  
+353 21 4378701

**E-mail address** pfizer-MSDS@pfizer.com

### 1.4. Emergency telephone number

**Emergency Telephone** Chemtrec 1-800-424-9300 International Chemtrec (24 hours):+1-703-527-3887

## Section 2: HAZARDS IDENTIFICATION

### 2.1. Classification of the substance or mixture

**Acute aquatic toxicity** Category 3

### 2.2. Label elements

**Hazard statements** H402 - Harmful to aquatic life

**Precautionary Statements** P273 - Avoid release to the environment  
P501 - Dispose of contents/container in accordance with all local and national regulations

### 2.3. Other hazards

**Other hazards** An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

**Note:** This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

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## Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 Substances

#### Substances

Not applicable

### 3.2 Mixtures

#### Hazardous

Chemical name	Weight-%	REACH Registration Number	EC No	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Cisatracurium besylate (CAS #: 96946-42-8)	<1.0		Not Listed	Aquatic Acute 3 (H402)	Not Listed	No data available	No data available
Benzenesulfonic acid (CAS #: 98-11-3)	**		202-638-7	Skin Corr 1C (H314) Dam 1 (H318)	Not Listed	No data available	No data available

#### NonHazardous

Chemical name	Weight-%	REACH Registration Number	EC No	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Water (CAS #: 7732-18-5)	95-100	-	231-791-2	Not classified as hazardous	Not Listed	No data available	No data available

### Full text of H- and EUH-phrases: see section 16

#### Acute Toxicity Estimate

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapor - mg/L	Inhalation LC50 - 4 hour - gas - ppm
Water 7732-18-5	89838.9	No data available	No data available	No data available	No data available
Benzenesulfonic acid 98-11-3	1100	No data available	No data available	No data available	No data available

### Additional information

\*\* to adjust pH

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

## Section 4: FIRST AID MEASURES

### 4.1. Description of first aid measures

#### Inhalation

Remove to fresh air. Seek immediate medical attention/advice.

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<b>Eye contact</b>	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
<b>Skin contact</b>	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
<b>Ingestion</b>	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

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

<b>Most important symptoms and effects</b>	For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.
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## **4.3. Indication of any immediate medical attention and special treatment needed**

<b>Note to physicians</b>	None.
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## **Section 5: FIRE-FIGHTING MEASURES**

### **5.1. Extinguishing media**

<b>Suitable Extinguishing Media</b>	Dry chemical, CO <sub>2</sub> , alcohol-resistant foam or water spray.
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### **5.2. Special hazards arising from the substance or mixture**

<b>Specific hazards arising from the chemical</b>	Fine particles (such as dust and mists) may fuel fires/explosions.
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<b>Hazardous combustion products</b>	Formation of toxic gases is possible during heating or fire.
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### **5.3. Advice for firefighters**

<b>Special protective equipment for fire-fighters</b>	Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.
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## **Section 6: ACCIDENTAL RELEASE MEASURES**

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

<b>Personal precautions</b>	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
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<b>For emergency responders</b>	Use personal protection recommended in Section 8.
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### **6.2. Environmental precautions**

<b>Environmental precautions</b>	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
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### **6.3. Methods and material for containment and cleaning up**

<b>Methods for containment</b>	Keep away from incompatible materials.
<b>Methods for cleaning up</b>	Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

<b>Prevention of secondary hazards</b>	Clean contaminated objects and areas thoroughly observing environmental regulations.
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### **6.4. Reference to other sections**

<b>Reference to other sections</b>	See section 8 for more information. See section 13 for more information.
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## Section 7: HANDLING AND STORAGE

### 7.1. Precautions for safe handling

#### Advice on safe handling

Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

**General hygiene considerations** Handle in accordance with good industrial hygiene and safety practice.

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

**Storage Conditions** Store as directed by product packaging.

### 7.3. Specific end use(s)

**Specific use(s)** Pharmaceutical product.

## Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1. Control parameters

#### Cisatracurium besylate

Pfizer OEL TWA-8 Hr: 30 (200 STEL)  $\mu\text{g}/\text{m}^3$

### 8.2. Exposure controls

**Engineering controls** Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

**Environmental exposure controls** No information available.

**Personal protective equipment** Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

**Eye/face protection** Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.).

**Hand protection** Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.).

**Skin and body protection** Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.).

**Respiratory protection** Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.).

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**General hygiene considerations** Handle in accordance with good industrial hygiene and safety practice.

## Section 9: PHYSICAL AND CHEMICAL PROPERTIES

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

Physical state	Sterile solution
Color	Colorless to Pale yellow
Odor	No information available.
Odor threshold	No information available
Molecular formula	Mixture
Molecular weight	Mixture

#### Property

#### Values

pH	No data available
Melting point / freezing point	No data available
Boiling point / boiling range	
Flash point	No information available
Evaporation rate	No data available
Flammability (solid, gas)	No data available
Flammability Limit in Air	
Upper flammability limit:	No data available
Lower flammability limit:	No data available
Vapor pressure	No data available
Vapor density	No data available
Relative density	No data available
Water solubility	No data available
Solubility(ies)	No data available
Partition coefficient	No data available
Autoignition temperature	No data available
Decomposition temperature	No data available
Kinematic viscosity	No data available
Dynamic viscosity	No data available
Particle characteristics	
Particle Size	No information available
Particle Size Distribution	No information available
Explosive properties	No information available

### 9.2. Other information

No information available

#### 9.2.1. Information with regard to physical hazard classes

No information available

#### 9.2.2. Other safety characteristics

No information available

## Section 10: STABILITY AND REACTIVITY

### 10.1. Reactivity

Reactivity No data available.

### 10.2. Chemical stability

Stability Stable under normal conditions.

#### Explosion data

Sensitivity to Mechanical Impact No data available.

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**Sensitivity to Static Discharge** No data available.

## **10.3. Possibility of hazardous reactions**

**Possibility of hazardous reactions** No information available.

## **10.4. Conditions to avoid**

**Conditions to avoid** Fine particles (such as dust and mists) may fuel fires/explosions.

## **10.5. Incompatible materials**

**Incompatible materials** As a precautionary measure, keep away from strong oxidizers.

## **10.6. Hazardous decomposition products**

**Hazardous decomposition products** No data available.

## **Section 11: TOXICOLOGICAL INFORMATION**

### **11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008**

<b>General Information:</b>	The information included in this section describes the potential hazards of the individual ingredients
<b>Short term</b>	Accidental ingestion may cause effects similar to those seen in clinical use.
<b>Known Clinical Effects:</b>	Adverse effects associated with therapeutic use include decreased heart rate (bradycardia), decrease in blood pressure (hypotension), flushing, difficulty breathing, skin rash, and neuromuscular block. Hypersensitivity reactions may also occur in susceptible individuals.
<b>Acute toxicity</b>	Based on available data, the classification criteria are not met.
<b>Serious eye damage/eye irritation</b>	Based on available data, the classification criteria are not met.
<b>Skin corrosion/irritation</b>	Based on available data, the classification criteria are not met.
<b>Respiratory or skin sensitization</b>	Based on available data, the classification criteria are not met.
<b>STOT - single exposure</b>	Based on available data, the classification criteria are not met.
<b>STOT - repeated exposure</b>	Based on available data, the classification criteria are not met.
<b>Reproductive toxicity</b>	Based on available data, the classification criteria are not met.
<b>Germ cell mutagenicity</b>	Based on available data, the classification criteria are not met.
<b>Carcinogenicity</b>	Based on available data, the classification criteria are not met.
<b>Aspiration hazard</b>	Based on available data, the classification criteria are not met.

### **Acute Toxicity: (Species, Route, End Point, Dose)**

#### **Benzenesulfonic acid**

Rat Oral LD50 > 1104 mg/kg

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Water	> 90 mL/kg ( Rat )	-	-
Benzenesulfonic acid	= 1100 mg/kg ( Rat )	-	-

**Acute Toxicity Comments:** A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

### **Irritation / Sensitization: (Study Type, Species, Severity)**

#### **Benzenesulfonic acid**

Skin irritation Rabbit Corrosive

Eye irritation Rabbit Corrosive

### **Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)**

#### **Cisatracurium besylate**

3 Week(s) Monkey Intravenous \* 3.75 mg/kg/day NOAEL None identified

3 Week(s) Dog Intravenous \* 2 mg/kg/day NOAEL None identified

### **Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))**

#### **Cisatracurium besylate**

Embryo / Fetal Development Rat Intravenous 4 mg/kg/day NOAEL Not teratogenic

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## Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

### Cisatracurium besylate

Bacterial Mutagenicity (Ames) *Salmonella* Negative  
*In Vitro* Cytogenetics Human Lymphocytes Negative  
*In Vitro* Cytogenetics Rat Bone marrow Negative  
*In Vitro* Mammalian Cell Mutagenicity Mouse Lymphoma Positive

**Carcinogenicity** None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

## 11.2. Information on other hazards

### 11.2.1. Endocrine disrupting properties

**Endocrine disrupting properties** No information available.

### 11.2.2. Other information

**Other adverse effects** No information available.

## Section 12: ECOLOGICAL INFORMATION

**Environmental Overview:** Environmental properties have not been thoroughly investigated. The following information is available for the individual ingredients.

### 12.1. Toxicity

#### Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

##### Cisatracurium besylate

*Daphnia magna* (Water Flea) OECD EC50 48 hours 14 mg/L

#### Bacterial Inhibition: (Inoculum, Method, End Point, Result)

##### Cisatracurium besylate

Activated sludge OECD IC50 > 4000 mg/L

### 12.2. Persistence and degradability

**Persistence and degradability** No information available.

#### Biodegradation: (Method, Inoculum, Biodeg Study, Result, Endpoint, Duration, Classification)

##### Cisatracurium besylate

OECD Ready 82.26 % After 28 Day(s) Ready

#### Photolysis: (Method, pH, Endpoint, Results)

##### Cisatracurium besylate

OECD 5 Half-Life 2.45 Day(s)

### 12.3. Bioaccumulative potential

**Bioaccumulation** No information available.

### 12.4. Mobility in soil

**Mobility in soil** No information available.

### 12.5. Results of PBT and vPvB assessment

**PBT and vPvB assessment**

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Chemical name	PBT and vPvB assessment
Benzenesulfonic acid	PBT assessment does not apply

## 12.6. Endocrine disrupting properties

**Endocrine disrupting properties** No information available.

## 12.7. Other adverse effects

No information available.

## Section 13: DISPOSAL CONSIDERATIONS

### 13.1. Waste treatment methods

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural wastewater and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

## Section 14: TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

**UN number:** Not applicable  
**UN proper shipping name:** Not applicable  
**Transport hazard class(es):** Not applicable  
**Packing group:** Not applicable  
**Environmental Hazard(s):** Not applicable

**Special precautions for user:** Not applicable

## Section 15: REGULATORY INFORMATION

### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Water

<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present
<b>EINECS</b>	231-791-2
<b>AICS</b>	Present

Cisatracurium besylate

<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>EINECS</b>	Not Listed
<b>Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)</b>	Schedule 4

Benzenesulfonic acid

<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
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**California Proposition 65**  
**TSCA**  
**EINECS**  
**AICS**

Not Listed  
Present  
202-638-7  
Present

## European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

## Authorizations and/or restrictions on use:

This product does not contain substances subject to authorization (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

## Persistent Organic Pollutants

Not applicable

## Ozone-depleting substances (ODS) regulation (EC) 1005/2009

Not applicable

### Legend:

**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory

**EINECS/ELINCS** - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

**AICS** - Australian Inventory of Chemical Substances

## 15.2. Chemical safety assessment

**Chemical Safety Report** No information available

## Section 16: OTHER INFORMATION

### Key or legend to abbreviations and acronyms used in the safety data sheet

#### Full text of H-Statements referred to under section 3

Hazardous to the aquatic environment, acute toxicity-Cat.3; H402 - Harmful to aquatic life; Skin corrosion/irritation-Cat.1C; H314 - Causes severe skin burns and eye damage Serious eye damage/eye irritation-Cat.1; H318 - Causes serious eye damage

#### Data Sources:

Safety data sheets for individual ingredients. Publicly available toxicity information. Pfizer proprietary drug development information.

#### Reason for revision

Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection.

#### Revision date

06-Dec-2021

#### Prepared By

Pfizer Global Environment, Health, and Safety

Pfizer Inc believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.