SAFETY DATA SHEET

1. Identification

Product identifier **Cisatracurium Besylate**

Other means of identification

Catalog number 1134118

CAS number 96946-42-8

Chemical name Isoquinolinium, 2,2'-[1,5-pentanediylbis[oxy(3-oxo-3,1-propanediyl]]bis [1-[(3,4-dimethoxyphenyl)methyl]-1,2,3,4-tetrahydro-6,7-dimethoxy-2-methyl-, dibenzenesulfonate, [1R-[1alpha,2alpha(1'R*,2'R*)]]-

Recommended use Specified quality tests and assay use only.

Recommended restrictions Not for use as a drug. Not for administration to humans or animals.

Manufacturer/Importer/Supplier/Distributor information

Manufacturer

Company name U. S. Pharmacopeia

Address 12601 Twinbrook Parkway
Rockville
MD
20852-1790
United States

Telephone RS Technical Services 301-816-8129

Website www.usp.org

E-mail RSTECH@usp.org

Emergency phone number CHEMTREC within US & Canada 1-800-424-9300
CHEMTREC outside US & Canada +1 703-527-3887

2. Hazard(s) identification

Physical hazards Not classified.

Health hazards

Acute toxicity, oral	Category 3
Acute toxicity, dermal	Category 2
Serious eye damage/eye irritation	Category 2B
Specific target organ toxicity, single exposure	Category 2 (neuromuscular system)

Environmental hazards Not classified.

OSHA defined hazards Not classified.

Label elements

Signal word Danger

Hazard statement Toxic if swallowed. Fatal in contact with skin. Causes eye irritation. May cause damage to organs (neuromuscular system).

Precautionary statement

Prevention Do not breathe dust/fume/gas/mist/vapors/spray. Do not get in eyes, on skin, or on clothing. Wear protective gloves/protective clothing. Wash thoroughly after handling.

Response If swallowed: Immediately call a poison center/doctor. Rinse mouth. If on skin: Wash with plenty of water. Immediately call a poison center/doctor. Take off immediately all contaminated clothing and wash it before reuse. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention. If exposed or concerned: Get medical advice/attention.

Storage Store locked up.

Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.
Hazard(s) not otherwise classified (HNOC)	This product is supplied in a small quantity which does not constitute a combustible dust hazard. The physical properties of this material indicate that in large quantities accumulated dust may be hazardous.
Supplemental information	Pharmacologically active material.

3. Composition/information on ingredients

Substance

Chemical name	Common name and synonyms	CAS number	%
Cisatracurium Besylate		96946-42-8	100

4. First-aid measures

Inhalation	If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Call a physician if symptoms develop or persist.
Skin contact	Rinse skin with water/shower. Get medical attention if irritation develops and persists. For minor skin contact, avoid spreading material on unaffected skin. Wash clothing separately before reuse.
Eye contact	Rinse with water. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists.
Ingestion	Rinse mouth thoroughly. If ingestion of a large amount does occur, call a poison control center immediately. Do not induce vomiting without advice from poison control center. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs. Do not use mouth-to-mouth method if substance is ingested. Induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device.
Most important symptoms/effects, acute and delayed	Muscle weakness. Pharmacologically active material. Occupational exposure may cause physiological effects.
Indication of immediate medical attention and special treatment needed	Provide general supportive measures and treat symptomatically. Treatment of neuromuscular blocking agent overdose may include the following: Administer an antidote such as edrophonium, neostigmine, and pyridostigmine to antagonize the action of the nondepolarizing neuromuscular blocking agent. Administer atropine or another suitable anticholinergic agent prior to or concurrently with the antagonist to counteract its cholinergic side effects. For hypotension, infuse isotonic fluid. If hypotension persists, administer dopamine or norepinephrine. For hypertension, sedate with benzodiazepines. For severe hypertension, nitroprusside is preferred. Labetalol, nitroglycerin, and phentolamine are alternatives. Monitor vital signs and EEG. For apnea or paralysis, maintain an adequate airway and administer ventilation until normal respiration is recovered. For shock or severe hypotension, administer fluids and vasopressors as needed. For ingestion, consider gastric lavage and/or administration of activated charcoal. (USP DI) (Poisindex)
General information	Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

5. Fire-fighting measures

Suitable extinguishing media	Water. Foam. Dry chemical or CO2. Use fire-extinguishing media appropriate for surrounding materials.
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	Explosion hazard: Avoid generating dust; fine dust dispersed in air in sufficient concentrations and in the presence of an ignition source is a potential dust explosion hazard.
Special protective equipment and precautions for firefighters	Wear suitable protective equipment.
Fire fighting equipment/instructions	Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Wear appropriate personal protective equipment. Avoid inhalation of dust from the spilled material. For personal protection, see section 8 of the SDS. Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.

Methods and materials for containment and cleaning up For waste disposal, see section 13 of the SDS. Avoid the generation of dusts during clean-up. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination.

Environmental precautions Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Avoid significant deposits of material, especially on horizontal surfaces, which may become airborne and form combustible dust clouds and may contribute to secondary explosions. Combustible dust clouds may be created where operations produce fine material (dust). Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential.

Conditions for safe storage, including any incompatibilities Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

8. Exposure controls/personal protection

Occupational exposure limits

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

Exposure limit values

Industrial Use

Material	Type	Value
Cisatracurium Besylate (CAS 96946-42-8)	STEL	170 micrograms/m3
	TWA	50 micrograms/m3

Biological limit values No biological exposure limits noted for the ingredient(s).

Appropriate engineering controls For laboratory operations, use local exhaust ventilation or a ventilated enclosure for high energy operations such as particle sizing. Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred.

Individual protection measures, such as personal protective equipment

Eye/face protection Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.

Skin protection

Hand protection Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent.

Other Train employees in proper gowning and degowning practices. Wear lab coat. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do not wear protective garments in common areas (e.g., cafeterias) or out-of-doors.

Respiratory protection Respirators are generally not required for laboratory operations. Use a tight-fitting full-face respirator with HEPA filters for spill cleanup. Chose respiratory protection appropriate to the task and the level of existing engineering controls.

Thermal hazards Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations Handling practices in this SDS are recommendations for laboratory use of reference standards. Procedures for any other uses or quantities should be determined after an appropriate assessment.

9. Physical and chemical properties

Appearance Appearance descriptions are general information and not specific to any USP lot.

Physical state Solid.

Form	Powder.
Color	White. Light yellow.
Odor	Odorless.
Odor threshold	Not available.
pH	Not available.
Melting point/freezing point	192.2 - 222.8 °F (89 - 106 °C)
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not available.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	Not available.
Vapor density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Not available.
Solubility (other)	Acetonitrile: Slightly soluble. Chloroform: Slightly soluble. Methanol: Slightly soluble.
Partition coefficient (n-octanol/water)	-2.12
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Chemical family	Benzylisoquinolinium.
Dust explosion properties	
Kst	181 bar.m/s
Minimum ignition energy (MIE) - dust cloud	< 2 mJ
Molecular formula	C65H82N2O18S2
Molecular weight	1243.48
pH in aqueous solution	6.2 - 6.5 Solution: 10%

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	None known.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions. NOx. SOx.

11. Toxicological information

Information on likely routes of exposure

Inhalation	Knowledge about health hazard is incomplete.
Skin contact	Fatal in contact with skin.
Eye contact	Causes eye irritation.
Ingestion	Toxic if swallowed. This material may cause: Muscle weakness.
Symptoms related to the physical, chemical, and toxicological characteristics	Muscle weakness. Irregular heartbeat. Low blood pressure.

Information on toxicological effects

Acute toxicity	Fatal in contact with skin. Toxic if swallowed.
Skin corrosion/irritation	Knowledge about health hazard is incomplete.
Serious eye damage/eye irritation	Causes eye irritation. In animal tests, a related material caused eye irritation.

Respiratory or skin sensitization

Respiratory sensitization	Knowledge about health hazard is incomplete.
Skin sensitization	Based on available data, the classification criteria are not met. A related material did not cause allergic skin reactions in animal tests.

Germ cell mutagenicity Knowledge about mutagenicity is incomplete.

Mutagenicity

Ames test
Result: Negative.
Micronucleus assay
Result: Negative.
Mutagenicity, In vitro human lymphocyte cytogenetics assay
Result: Negative.
Mutagenicity, Mouse lymphoma assay
Result: Equivocal.
Mutagenicity, Rat bone marrow cytogenetics assay
Result: Negative.

Carcinogenicity Knowledge about carcinogenicity is incomplete.

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

Reproductive toxicity Based on available data, the classification criteria are not met.

Reproductivity

0.5 - 1 mg/kg Reproductivity, administered intravenously
Result: Negative.
Species: Rat
4 mg/kg/day Reproductivity, administered subcutaneously
Result: Negative.
Species: Rat

Specific target organ toxicity - single exposure	May cause damage to organs (neuromuscular system).
Specific target organ toxicity - repeated exposure	Knowledge about health hazard is incomplete.
Aspiration hazard	Based on available data, the classification criteria are not met.
Further information	Pharmacologically active material. Occupational exposure may cause physiological effects.

12. Ecological information

Ecotoxicity

Product		Species	Test Results
Cisatracurium Besylate (CAS 96946-42-8)			
Aquatic			
Crustacea	EC40	Water flea (Daphnia magna)	14 mg/l, 48 hours

Persistence and degradability Expected to be readily biodegradable.

Bioaccumulative potential

Octanol/water partition coefficient log Kow
-2.12

Mobility in soil No data available.

Other adverse effects No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal considerations

Disposal instructions Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste.

Local disposal regulations Dispose in accordance with all applicable regulations.

Hazardous waste code The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

Waste from residues / unused products Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

Contaminated packaging Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT

UN number UN2811
UN proper shipping name Toxic solid, organic, n.o.s. (Cisatracurium Besylate)
Transport hazard class(es)
Class 6.1
Subsidiary risk -
Packing group II

IATA

UN number UN2811
UN proper shipping name Toxic solid, organic, n.o.s. (Cisatracurium Besylate)
Transport hazard class(es)
Class 6.1
Subsidiary risk -
Packing group II
Other information
Passenger and cargo aircraft Allowed with restrictions.
Cargo aircraft only Allowed with restrictions.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not applicable.

DOT; IATA

General information It is the shipper's responsibility to determine the correct transport classification at the time of shipment.

15. Regulatory information

US federal regulations This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - Yes
Delayed Hazard - No
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical Yes

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA) Not regulated.

US state regulations California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No

Country(s) or region	Inventory name	On inventory (yes/no)*
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)
A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date 01-24-2014

Revision date 09-19-2018

Version # 04

Further information Refer to NFPA 654, Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids, for safe handling.

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