



Meitheal Pharmaceuticals, Inc.

Safety Data Sheet

SDS Title: Atracurium Besylate Injection Safety Data Sheet	SDS Number: SDS-000003	Page Number: 1 of 8
Function: Regulatory Affairs	Effective Date: May 15, 2020	Version Number: 2.0

## SECTION 1: IDENTIFICATION

### 1.1. Product Identifier

**Product Form:** Mixture

**Product Name:** Atracurium Besylate Injection, USP (10mg/mL)

**Chemical Name:** 2-(2-Carboxyethyl)-1, 2, 3, 4-tetrahydro-6, 7-dimethoxy-2-methyl-1-veratrylisoquinolinium benzene sulfonate, pentamethylene ester

**Formula:** C<sub>65</sub>H<sub>82</sub>N<sub>2</sub>O<sub>18</sub>S<sub>2</sub>

**Note:** 5 mL solution in a 5 mL vial (single-dose), 10 mL solution in a 10 mL vial (multi-dose)

### 1.2. Intended Use of the Product

**Use of the Substance/Mixture:** Benzylisoquinoline. Neuro-muscular blocking agent. For professional use only.

### 1.3. Name, Address, and Telephone of the Responsible Party

#### Company

Meitheal Pharmaceuticals, Inc.  
8700 W. Bryn Mawr, Suite 600S  
Chicago, IL 60631  
224-443-4617

[www.meithealpharma.com](http://www.meithealpharma.com)

### 1.4. Emergency Telephone Number

**Emergency Number** : 844-824-8426

## SECTION 2: HAZARDS IDENTIFICATION

### 2.1. Classification of the Substance or Mixture

Not classified

### 2.2. Label Elements

#### GHS-US Labeling

No labeling applicable

### 2.3. Other Hazards

Exposure may aggravate pre-existing eye, skin, or respiratory conditions.

### 2.4. Unknown Acute Toxicity (GHS-US)

No data available

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1. Substance

Not applicable

### 3.2. Mixture

Name	Product Identifier	%	GHS-US classification
Water	(CAS-No.) 7732-18-5	98.9	Not classified

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Atracurium besilate	(CAS-No.) 64228-81-5	1	Acute Tox. 3 (Oral), H301
Benzyl alcohol	(CAS-No.) 100-51-6	< 0.1	Flam. Liq. 4, H227 Acute Tox. 4 (Oral), H302 Acute Tox. 4 (Inhalation:dust,mist), H332 Eye Irrit. 2A, H319 Aquatic Acute 2, H401
Benzenesulfonic acid	(CAS-No.) 98-11-3	< 0.1	Met. Corr. 1, H290 Acute Tox. 4 (Oral), H302 Skin Corr. 1C, H314 Eye Dam. 1, H318

Full text of H-phrases: see section 16

## SECTION 4: FIRST AID MEASURES

### 4.1. Description of First-aid Measures

**First-aid Measures General:** Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice.

**First-aid Measures After Inhalation:** When symptoms occur: go into open air and ventilate suspected area. Obtain medical attention if breathing difficulty persists.

**First-aid Measures After Skin Contact:** Remove contaminated clothing. Drench affected area with water for at least 5 minutes. Obtain medical attention if irritation develops or persists.

**First-aid Measures After Eye Contact:** Rinse cautiously with water for at least 5 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention if irritation develops or persists.

**First-aid Measures After Ingestion:** Rinse mouth. Do NOT induce vomiting. Obtain medical attention.

### 4.2. Most Important Symptoms and Effects Both Acute and Delayed

**Symptoms/Injuries:** Not expected to present a significant hazard under anticipated conditions of normal use. Please refer to the package insert for more detailed information. Common clinical side effects include: histamine release in susceptible patients, vasodilatation (flushing), hypotension, bronchospasm, allergic reactions (anaphylactic or anaphylactoid responses), hypertension, tachycardia, bradycardia, dyspnoea, laryngospasm, rash, urticaria, reactions at injection site.

**Symptoms/Injuries After Inhalation:** Prolonged exposure may cause irritation.

**Symptoms/Injuries After Skin Contact:** Prolonged exposure may cause skin irritation.

**Symptoms/Injuries After Eye Contact:** May cause slight irritation to eyes.

**Symptoms/Injuries After Ingestion:** Potent pharmaceutical- ingestion may be harmful or have adverse effects.

**Chronic Symptoms:** None expected under normal conditions of use.

### 4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

If exposed or concerned, get medical advice and attention. If medical advice is needed, have product container or label at hand.

## SECTION 5: FIRE-FIGHTING MEASURES

### 5.1. Extinguishing Media

**Suitable Extinguishing Media:** Use extinguishing media appropriate for surrounding fire.

**Unsuitable Extinguishing Media:** Do not use a heavy water stream. Use of heavy stream of water may spread fire.

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## 5.2. Special Hazards Arising From the Substance or Mixture

**Fire Hazard:** Not considered flammable but may burn at high temperatures.

**Explosion Hazard:** Product is not explosive.

**Reactivity:** Hazardous reactions will not occur under normal conditions.

## 5.3. Advice for Firefighters

**Precautionary Measures Fire:** Exercise caution when fighting any chemical fire.

**Firefighting Instructions:** Use water spray or fog for cooling exposed containers.

**Protection During Firefighting:** Do not enter fire area without proper protective equipment, including respiratory protection.

**Hazardous Combustion Products:** Nitrogen oxides. Sulfur oxides. Carbon oxides (CO, CO<sub>2</sub>).

## SECTION 6: ACCIDENTAL RELEASE MEASURES

### 6.1. Personal Precautions, Protective Equipment and Emergency Procedures

**General Measures:** Avoid prolonged contact with eyes, skin and clothing. Avoid breathing (vapor, mist, spray).

#### 6.1.1. For Non-Emergency Personnel

**Protective Equipment:** Use appropriate personal protective equipment (PPE).

**Emergency Procedures:** Evacuate unnecessary personnel.

#### 6.1.2. For Emergency Personnel

**Protective Equipment:** Equip cleanup crew with proper protection.

**Emergency Procedures:** Upon arrival at the scene, a first responder is expected to recognize the presence of dangerous goods, protect oneself and the public, secure the area, and call for the assistance of trained personnel as soon as conditions permit. Ventilate area.

### 6.2. Environmental Precautions

Prevent entry to sewers and public waters.

### 6.3. Methods and Materials for Containment and Cleaning Up

**For Containment:** Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams.

**Methods for Cleaning Up:** Clean up spills immediately and dispose of waste safely. Transfer spilled material to a suitable container for disposal. Contact competent authorities after a spill.

### 6.4. Reference to Other Sections

See Section 8 for exposure controls and personal protection and Section 13 for disposal considerations.

## SECTION 7: HANDLING AND STORAGE

### 7.1. Precautions for Safe Handling

**Precautions for Safe Handling:** Patients should adhere to the instructions provided within the product information insert or product label for appropriate consumer-specific information about this product when used according to the physician's directions. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Avoid prolonged contact with eyes, skin and clothing. Avoid breathing vapors, mist, spray.

**Hygiene Measures:** This SDS is for a pharmaceutical agent - Handling of this product in its final form presents minimal occupational exposure risk. In an occupational setting, handle in accordance with good industrial hygiene and safety procedures. Avoid contact with eyes, skin and clothing. Avoid breathing vapor or mist. Use appropriate personal protective equipment when handling and observe good personal hygiene measures after handling.

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## 7.2. Conditions for Safe Storage, Including Any Incompatibilities

**Technical Measures:** Comply with applicable regulations.

**Storage Conditions:** Keep container closed when not in use. Store in a dry, cool place. Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials.

**Incompatible Materials:** Strong acids, strong bases, strong oxidizers. Water reactive materials.

## 7.3. Specific End Use(s)

Benzylisoquinoline. Neuro-muscular blocking agent. For professional use only.


# SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

## 8.1. Control Parameters

For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), AIHA (WEEL), NIOSH (REL), or OSHA (PEL).

Benzyl alcohol (100-51-6)		
USA AIHA	WEEL TWA (ppm)	10 ppm

## 8.2. Exposure Controls

- Appropriate Engineering Controls** : Suitable eye/body wash equipment should be available in the vicinity of any potential exposure. Ensure adequate ventilation, especially in confined areas. Ensure all national/local regulations are observed.
- Personal Protective Equipment** : Gloves. Protective clothing. Protective goggles.
- 
- Materials for Protective Clothing** : Chemically resistant materials and fabrics.
- Hand Protection** : Wear protective gloves.
- Eye and Face Protection** : Chemical safety goggles.
- Skin and Body Protection** : Wear suitable protective clothing.
- Respiratory Protection** : If exposure limits are exceeded or irritation is experienced, approved respiratory protection should be worn. In case of inadequate ventilation, oxygen deficient atmosphere, or where exposure levels are not known wear approved respiratory protection.
- Other Information** : When using, do not eat, drink or smoke.

# SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

## 9.1. Information on Basic Physical and Chemical Properties

- Physical State** : Liquid
- Appearance** : Clear, colorless solution
- Odor** : No data available
- Odor Threshold** : No data available
- pH** : 3.25 - 3.65
- Evaporation Rate** : No data available
- Melting Point** : No data available

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Freezing Point	:	No data available
Boiling Point	:	No data available
Flash Point	:	No data available
Auto-ignition Temperature	:	No data available
Decomposition Temperature	:	No data available
Flammability (solid, gas)	:	Not applicable
Vapor Pressure	:	No data available
Relative Vapor Density at 20°C	:	No data available
Relative Density	:	No data available
Solubility	:	Soluble in water
Partition Coefficient: N-Octanol/Water	:	No data available
Viscosity	:	No data available

9.2. Other Information No additional information available

## SECTION 10: STABILITY AND REACTIVITY

- 10.1. **Reactivity:** Hazardous reactions will not occur under normal conditions.
- 10.2. **Chemical Stability:** Stable under recommended handling and storage conditions (see section 7).
- 10.3. **Possibility of Hazardous Reactions:** Hazardous polymerization will not occur.
- 10.4. **Conditions to Avoid:** Direct sunlight, extremely high or low temperatures, and incompatible materials.
- 10.5. **Incompatible Materials:** Strong acids, strong bases, strong oxidizers. Water reactive materials.
- 10.6. **Hazardous Decomposition Products:** None expected under normal conditions of use.

## SECTION 11: TOXICOLOGICAL INFORMATION

### 11.1. Information on Toxicological Effects

Acute Toxicity: Not classified

<b>Benzyl alcohol (100-51-6)</b>	
LD50 Oral Rat	1230 mg/kg
LD50 Dermal Rabbit	> 2000 mg/kg
LC50 Inhalation Rat	> 4.178 mg/l/4h
<b>Benzenesulfonic acid (98-11-3)</b>	
LD50 Oral Rat	1004 mg/kg
LD50 Dermal Rat	> 2000 mg/kg
<b>Atracurium besilate (64228-81-5)</b>	
ATE (Oral)	100.00 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

**Specific Target Organ Toxicity (Single Exposure):** Not classified

**Specific Target Organ Toxicity (Repeated Exposure):** Not classified

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**Aspiration Hazard:** Not classified

**Symptoms/Injuries After Inhalation:** Prolonged exposure may cause irritation.

**Symptoms/Injuries After Skin Contact:** Prolonged exposure may cause skin irritation.

**Symptoms/Injuries After Eye Contact:** May cause slight irritation to eyes.

**Symptoms/Injuries After Ingestion:** Potent pharmaceutical- ingestion may be harmful or have adverse effects.

**Chronic Symptoms:** None expected under normal conditions of use.

## SECTION 12: ECOLOGICAL INFORMATION

### 12.1. Toxicity

Ecology - General : Not classified.

<b>Benzyl alcohol (100-51-6)</b>	
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])
ErC50 (Algae)	770 mg/l

### 12.2. Persistence and Degradability

<b>Atracurium Besylate Injection, USP (10mg/mL)</b>	
Persistence and Degradability	Not established.

### 12.3. Bioaccumulative Potential

<b>Atracurium Besylate Injection, USP (10mg/mL)</b>	
Bioaccumulative Potential	Not established.
<b>Benzyl alcohol (100-51-6)</b>	
Log Pow	1.1

12.4. **Mobility in Soil** No additional information available

### 12.5. Other Adverse Effects

Other Information : Avoid release to the environment.

## SECTION 13: DISPOSAL CONSIDERATIONS

### 13.1. Waste Treatment Methods

**Waste Disposal Recommendations:** Dispose of contents/container in accordance with local, regional, national, and international regulations.

**Ecology - Waste Materials:** Avoid release to the environment.

## SECTION 14: TRANSPORT INFORMATION

The shipping description(s) stated herein were prepared in accordance with certain assumptions at the time the SDS was authored, and can vary based on a number of variables that may or may not have been known at the time the SDS was issued.

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- 14.1. **In Accordance with DOT** Not regulated for transport
- 14.2. **In Accordance with IMDG** Not regulated for transport
- 14.3. **In Accordance with IATA** Not regulated for transport

**SECTION 15: REGULATORY INFORMATION**

**15.1. US Federal Regulations**

<b>Water (7732-18-5)</b>
Listed on the United States TSCA (Toxic Substances Control Act) inventory
<b>Benzyl alcohol (100-51-6)</b>
Listed on the United States TSCA (Toxic Substances Control Act) inventory
<b>Benzenesulfonic acid (98-11-3)</b>
Listed on the United States TSCA (Toxic Substances Control Act) inventory

**15.2. US State Regulations**

<b>Benzyl alcohol (100-51-6)</b>
U.S. - Massachusetts - Right To Know List U.S. - Pennsylvania - RTK (Right to Know) List
<b>Benzenesulfonic acid (98-11-3)</b>
U.S. - New Jersey - Right to Know Hazardous Substance List

**SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION**

**Date of Preparation or Latest Revision** 05/15/2020  
**Other Information** This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200

**GHS Full Text Phrases:**

Acute Tox. 3 (Oral)	Acute toxicity (oral) Category 3
Acute Tox. 4 (Inhalation:dust,mist)	Acute toxicity (inhalation:dust,mist) Category 4
Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
Aquatic Acute 2	Hazardous to the aquatic environment - Acute Hazard Category 2
Eye Dam. 1	Serious eye damage/eye irritation Category 1
Eye Irrit. 2A	Serious eye damage/eye irritation Category 2A
Flam. Liq. 4	Flammable liquids Category 4

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Met. Corr. 1	Corrosive to metals Category 1
Skin Corr. 1C	Skin corrosion/irritation Category 1C
H227	Combustible liquid
H290	May be corrosive to metals
H301	Toxic if swallowed
H302	Harmful if swallowed
H314	Causes severe skin burns and eye damage
H318	Causes serious eye damage
H319	Causes serious eye irritation
H332	Harmful if inhaled
H401	Toxic to aquatic life

*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.*