

## SAFETY DATA SHEETS

**This SDS packet was issued with item:**

078941768

N/A

# Bethanechol Chloride Tablets, USP

## 5 mg, 10 mg, 25 mg and 50 mg

### ECI Pharmaceuticals, LLC

### Safety Data Sheet



Revision date: 1 April 2020  
Print date: 1 April 2020  
Version: Rev 1

## 1. Product and Company Identification

### 1.1 Product identifiers

Product Name	Bethanechol Chloride Tablets, USP, 5 mg
Strength	5 mg, 10 mg, 25 mg and 50 mg
Producer	ECI Pharmaceuticals
NDC Number (Pack size)	5 mg 51293-645-01 (100 tablets) 10 mg 51293-646-01 (100 tablets) 25 mg 51293-647-01 (100 tablets) 50 mg 51293-648-01 (100 tablets)

### 1.2 Identified uses of the product and uses advised against

Identified Uses	Urinary Retention.
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### 1.3 Details of the chemical supplier

Company	ECI Pharmaceuticals, LLC
Address	5311 NW 35 <sup>th</sup> Terrace, Fort Lauderdale, FL 33309 USA

### 1.4 Emergency phone number

Emergency phone number	1-800-222-1222
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## 2. Hazards Identification

### 2.1 Classification of the substance or mixture

GHS Class	Acute Toxicity (oral) - Category 4
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### 2.2 GHS Label elements, including precautionary statements

Label elements	The substance is classified and labelled according to the Global Harmonized System (GHS)
GHS Pictograms	



Signal word	Warning
Hazard statements	Harmful if swallowed.
Precautionary statements	Wash thoroughly after handling Material may be irritating to the mucous membranes and upper respiratory tract. May be harmful by inhalation or skin absorption. May cause eye, skin, or respiratory system irritation If medical advice is needed, have product container or label at hand.

### 2.3 Hazards not otherwise classified (HNOC) or not covered by GHS - None

### 3. Composition/Information on Ingredients

Ingredient	CAS Number	GHS Classification	%
Bethanechol Chloride, USP	590-63-6	Not Listed	1.43 – 11.36%
Lactose Anhydrous	63-42-3	Not Listed	*
Microcrystalline Cellulose	9004-34-6	Not Listed	*
Sodium starch Glycolate	9063-38-1	Not Listed	*
Magnesium Stearate	577-04-0	Not Listed	*
Colloidal Silicon Dioxide	7631-86-9	Not Listed	*

Remarks

\* Proprietary

### 4. First Aid Measures

#### 4.1 Description of first aid measures

General advice	Immediately remove any clothing soiled with this product. Remove breathing apparatus only after contaminated clothing have been completely removed. In case of irregular breathing or respiratory arrest provide artificial respiration.
Skin contact	Immediately wash skin with soap and plenty of water for at least 15 minutes. Remove contaminated clothing. Get medical attention if symptoms occur. Wash clothing before reuse.
Eye contact	Hold eyelids apart and flush eyes with plenty of water for at least 15 minutes. Have eyes examined and tested by medical personnel.
Inhalation	Remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Get immediate medical attention.
Ingestion	Wash out mouth with water provided person is conscious. Never give anything by mouth to an unconscious person. Get medical attention. Do NOT induce vomiting unless directed to do so by medical personnel.

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

Symptoms and effects No data available

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

Other first aid No data available

### 5. Fire Fighting Measures

#### 5.1 Suitable (and unsuitable) extinguishing media

Suitable extinguishing media Use alcohol-resistant foam, carbon dioxide, water, or dry chemical spray

#### 5.2 Special hazards arising from the substance or mixture

Special hazards No data available.

#### 5.3 Advice for firefighters

Protective equipment As in any fire, wear self-contained breathing apparatus pressure-demand (NIOSH approved or equivalent), and full protective gear to prevent contact with skin and eyes

### 6. Accidental Release Measures

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

Personal precautions Avoid raising and breathing dust, and provide adequate ventilation. As conditions warrant, wear a NIOSH approved self-contained breathing apparatus, or respirator, and appropriate personal protection (rubber boots, safety goggles, and heavy rubber gloves).

#### 6.2 Environmental precautions

Environmental precautions Take steps to avoid release into the environment, if safe to do so.

#### 6.3 Methods and materials for containment and cleaning up

Methods for cleanup Contain spill and collect, as appropriate. Transfer to a chemical waste container for disposal in accordance with local regulations.

#### 6.4 References to other sections

Other references For safe handling see section 7.  
For information on personal protection equipment see section 8.

## 7. Handling and Storage

### 7.1 General hygiene considerations

**General hygiene** Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. See also Section 8 for additional information on hygiene measures. Remove contaminated clothing and protective equipment before entering eating areas.

### 7.2 Precautions for safe handling

**Safe handling precautions** Avoid breathing dust/fume/gas/mist/vapors/spray. Avoid prolonged or repeated exposure..

### 7.3 Conditions for safe storage, including any incompatibilities

**Storage conditions** Keep container tightly closed. Store in accordance with information listed on the product insert. Dispense in tight, light-resistant containers as defined in USP/NF with a child-resistant closure.

**Incompatible Materials** None

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

## 8. Exposure Controls/Personal Protection

### 8.1 Control and exposure limits recommended by the chemical manufacturer

**OSHA Standards** During manufacturing: Follow the OSHA (US) respirator regulations found in 29 CFR 1910.134

**Threshold Limit Values** No data available

**NIOSH Recommendations** During manufacturing: Use a NIOSH (US) approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced.

### 8.2 Appropriate engineering controls

**Engineering controls** Use process enclosures, local exhaust ventilation, or other engineering controls to control airborne levels below recommended exposure limits.

### 8.3 Individual protection measures, such as personal protective equipment

**Respiratory protection** NIOSH approved respirator, as conditions warrant

**Eye/face protection** Safety glasses

**Hand protection** Compatible chemical-resistant gloves.

**Body protection** Lab coat

## 9. Physical and Chemical Properties

### 9.1 Information on basic physical and chemical properties

a) **Physical State** Solid

b) **Appearance**

5 mg	White Round, Flat-Faced, Beveled Edge Tablet, debossed with 'ECI' above the score and '645' below the score on one side and plain on the other side
10 mg	White Round, Flat-Faced, Beveled Edge Tablet, debossed with 'ECI' above the score and '646' below the score on one side and plain on the other side
25 mg	Yellow Round, Flat-Faced, Beveled Edge Tablet, debossed with 'ECI' above the score and '647' below the score on one side and plain on the other side
50 mg	Yellow Round, Flat-Faced, Beveled Edge Tablet, debossed with 'ECI' above the score and '648' below the score on one side and plain on the other side

c) **Odor** No data available

d) **Odor threshold** No data available

e) **pH** No data available

f) **Melting/Freezing point** No data available

g) **Boiling point** No data available

h) **Flash point** No data available

i) **Evaporation rate** No data available

j) **Flammability (solid, gas)** No data available

k) **Upper/lower flammability or explosive limits** Upper (UEL): No data available  
Lower (LEL): No data available

l) **Vapor pressure** No data available

m) **Vapor density** No data available

n) **Relative density** No data available

o) **Water solubility** No data available

p) **Partition coefficient octanol/water** No data available

q) Auto-ignition temp	No data available
r) Decomposition temp	No data available
s) Viscosity	No data available

## 10. Stability and Reactivity

<b>10.1 Reactivity</b>	
Reactivity	No data available
<b>10.2 Chemical stability</b>	
Chemical stability	Stable under normal conditions of use and storage.
<b>10.3 Possibility of hazardous reactions</b>	
Hazardous reactions	No data available
<b>10.4 Conditions to avoid</b>	
Conditions to avoid	No data available
<b>10.5 Incompatible materials</b>	
Incompatible materials	Keep away from carbon dioxide, carbon monoxide, Hydrogen chloride gas and Nitrogen oxide.
<b>10.6 Hazardous decomposition products</b>	
Hazardous products	No data available

## 11. Toxicological Information

### 11.1 Information on toxicological effects

#### Acute toxicity

Acute administration toxicity	<b>Bethanechol Chloride</b> LD50 Rat Oral – 1500 mg/kg LD50 Rat Subcutaneous – 175 mg/kg LD50 Mouse Oral – 250 mg/kg LD50 Mouse Intraperitoneal – 120 mg/kg  <b>Microcrystalline Cellulose</b> LD50 Rat Oral - > 3160mg/kg LD50 Rabbit Dermal - > 2000 mg/kg  <b>Colloidal Silicon Dioxide</b> LD50 Rat Oral - 3160 mg/kg  <b>Lactose Anhydrous</b> LD50 Rat Oral - >10 g/kg LD50 Rat Intraperitoneal - >10 g/kg LD50 Rat Subcutaneous - >5 g/kg  <b>Sodium Starch Glycolate</b> LD50 Rat Oral – No data available  <b>Magnesium Stearate</b> LD50 Rat Oral - >10 g/kg
Acute dermal toxicity	No data available
Acute inhalation toxicity	<b>Magnesium Stearate</b> LD50 Rat Oral - >2 mg/L

#### Skin corrosion/irritation

Skin corrosion irritation	No irritant effect
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#### Serious eye damage/eye irritation

Eye damage/eye irritation	No irritating effect
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#### Respiratory or skin sensitization

Respiratory sensitizer	No data available
Skin sensitizer	No data available

#### Germ cell mutagenicity

Mutagenicity	No data available
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**Suspected cancer agent**

ACGIH	Substance not listed
NTP	Substance not listed
OSHA	Substance not listed
IARC	Substance not listed

**Reproductive toxicity**

Reproductive toxicity	No data available
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**Aspiration hazard**

Aspiration hazard	No data available
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**12. Ecological Information****12.1 Ecotoxicity (aquatic and terrestrial)**

Ecotoxicity	Avoid release into the environment. Runoff from fire control or dilution water may cause pollution.
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**12.2 Persistence and degradability**

Degradability	No data available
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**12.3 Bioaccumulation potential**

Bioaccumulation	No data available
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**12.4 Mobility in soil**

Mobility in soil	No data available
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**12.5 Results of PBT and vPvB assessment**

PBT/vPvB assessment	Not available as chemical safety assessment not required/not conducted.
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**13. Disposal Considerations****13.1 Waste treatment methods**

Waste treatment disposal	Dispose in accordance with local, state, and federal regulations.
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**14. Transport Information****14.1 Transport Hazard Class(s)**

UN Number	Not available
DOT	Not available
IMDG	Not available
IATA	Not available

**14.2 Packaging Group**

DOT, ADR, IMDG, IATA	Not available
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**15. Regulatory Information****15.1 Safety, health, and environmental regulations specific to the product or mixture**

DEA Schedule	Not regulated, Prescription Drug Product
Other Regulations	Not available

**16. Other Information**

HMIS Rating	Health hazard: 1 Flammability: 0 Physical Hazard: 0
NFPA Rating	Health hazard: 1 Fire Hazard: 0 Reactivity Hazard: 0
Revision Date	1 April 2020



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Abbreviations and acronyms

IMDG - International Maritime Code for Dangerous Goods  
TDG - Transportation of Dangerous Goods  
IATA - International Air Transport Association  
GHS - Globally Harmonized System of Classification and Labelling of Chemicals  
PBT - Persistent, bioaccumulative and toxic assessment  
vPvB - Very persistent and very bioaccumulative assessment  
ACGIH - American Conference of Governmental Industrial Hygienists  
NIOSH - National Institute for Occupational Safety and Health  
CAS - Chemical Abstracts Service (division of the American Chemical Society)  
NFPA - National Fire Protection Association  
HMIS - Hazardous Materials Identification System  
CFR - Code of Federal Regulations  
SARA - Superfund Amendments and Reauthorization Act  
DOT - US Department of Transportation  
LD50 - Median lethal dose  
SDS - Safety Data Sheet