# U.S. Pharmacopeial Convention

# SAFETY DATA SHEET

# 1. Identification

Product identifier Bethanechol Chloride

Other means of identification

Catalog number 1071009 CAS number 590-63-6

Synonyms Carbamylmethylcholine chloride

Chemical name (±)-(2-Hydroxypropyl)trimethylammonium chloride carbamate

**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 & 1-800-424-9300

Canada

CHEMTREC outside US & +1 703-527-3887

Canada

2. Hazard(s) identification

Physical hazards Not classified.

Health hazards Acute toxicity, oral Category 4

Environmental hazards Not classified.

OSHA defined hazards Not classified.

Label elements



Signal word Warning

Hazard statement Harmful if swallowed.

**Precautionary statement** 

**Prevention** Wash thoroughly after handling.

**Response** If swallowed: Call a poison center/doctor if you feel unwell. Rinse mouth.

Storage Not available.

**Disposal** Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazard(s) not otherwise

classified (HNOC)

None known.

**Supplemental information** Pharmacologically active material.

3. Composition/information on ingredients

Substance

Material name: Bethanechol Chloride

USP SDS US

% Common name and synonyms CAS number Chemical name Bethanechol Chloride Carbamylmethylcholine chloride 590-63-6 100

# 4. First-aid measures

Inhalation Move to fresh air. Call a physician if symptoms develop or persist.

Wash off with soap and water. Get medical attention if irritation develops and persists. Skin contact

Rinse with water. Get medical attention if irritation develops and persists. Eye contact

Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately. Ingestion

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.

Most important

symptoms/effects, acute and delaved

Indication of immediate

Cardiovascular effects. Central nervous system effects. Pharmacologically active material.

Occupational exposure may cause physiological effects.

Treat symptomatically. Treatment of cholinergic agonist overdose may include the following: Administer activated charcoal as a slurry unless contraindicated. This is most effective when medical attention and special administered within one hour of ingestion. For muscarinic symptoms, administer atropine sulfate treatment needed intravenously. For bronchospasm, administer epinephrine. Inhaled beta-agonist bronchodilators may reverse bronchoconstriction. Systemic corticosteroids may be needed. For lung injury, maintain ventilation and oxygenation by employing early use of PEEP and mechanical ventilation if needed. Monitor arterial blood gas frequently. For seizures, administer a benzodiazepine intravenously, followed by phenobarbital or propofol if the seizures recur. Monitor for hypotension,

> dysrhythmias, respiratory depression, and need for endotracheal intubation. Evaluate for hypoglycemia, electrolyte disturbances, hypoxia.

Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from **General information** 

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

Water. Foam. Dry chemical or CO2. Use fire-extinguishing media appropriate for surrounding Suitable extinguishing media

materials.

Unsuitable extinguishing

media

None known.

Specific hazards arising from

the chemical

No unusual fire or explosion hazards noted.

Wear suitable protective equipment.

Special protective equipment

and precautions for firefighters

Fire fighting equipment/instructions

Specific methods

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.

Use standard firefighting procedures and consider the hazards of other involved materials. Cool

containers exposed to flames with water until well after the fire is out.

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. Wear appropriate personal protective equipment. Avoid inhalation of dust from the spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. For personal protection, see section 8 of the SDS.

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. Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential.

Material name: Bethanechol Chloride USP SDS US 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

No exposure limits noted for ingredient(s).

**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.

Train employees in proper gowning and degowning practices. Wear lab coat. Base the choice of Other

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

Handle in accordance with good industrial hygiene and safety practice. 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

Form Crystalline powder.

White. Color Odor Faint odor. **Odor threshold** Not available. Not available. pН

424.4 - 426.2 °F (218 - 219 °C) (decomposes) Melting point/freezing point

Initial boiling point and boiling

range

Not available.

Flash point Not available. **Evaporation rate** Not available. Not available. Flammability (solid, gas) Upper/lower flammability or explosive limits

Flammability limit - lower

Not available.

(%)

Flammability limit - upper

Not available.

Not available. Explosive limit - lower (%) Explosive limit - upper (%) Not available.

< 0.0000001 kPa at 25 °C Vapor pressure

Vapor density Not available. Not available. Relative density

Solubility(ies)

Freely soluble. Solubility (water) Solubility (other) Ether: Insoluble. Chloroform: Insoluble. Alcohol: Freely soluble.

Not available. Auto-ignition temperature **Decomposition temperature** Not available. Not available. **Viscosity** 

Other information

**Chemical family** Quaternary amine. Molecular formula C7H17CIN2O2

196.67 Molecular weight

pH in aqueous solution 5.5 - 6.5 Solution: 1%

# 10. Stability and reactivity

The product is stable and non-reactive under normal conditions of use, storage and transport. Reactivity

Contact with incompatible materials.

**Chemical stability** Material is stable under normal conditions.

Possibility of hazardous

Conditions to avoid

reactions

No dangerous reaction known under conditions of normal use.

Incompatible materials None known.

**Hazardous decomposition** 

products

NOx. Cl-. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

# 11. Toxicological information

## Information on likely routes of exposure

Knowledge about health hazard is incomplete. Inhalation Knowledge about health hazard is incomplete. Skin contact Knowledge about health hazard is incomplete. Eye contact

Ingestion Harmful if swallowed. Based on information from therapeutic use, this material may cause:

Cardiovascular effects. Central nervous system effects.

Symptoms related to the

physical, chemical, and

toxicological characteristics Cholinergic agonists: Gastrointestinal disturbances. Central nervous system stimulation. Difficulty

breathing. Muscle cramps or weakness. Sweating. Tearing.

# Information on toxicological effects

**Acute toxicity** Harmful if swallowed.

**Product Species Test Results** 

Bethanechol Chloride (CAS 590-63-6)

Oral

LD50 Mouse 250 mg/kg Rat 1500 mg/kg

Skin corrosion/irritation Knowledge about health hazard is incomplete. Serious eye damage/eye

irritation

Knowledge about health hazard is incomplete.

Respiratory or skin sensitization

Respiratory sensitization Knowledge about health hazard is incomplete. Skin sensitization Knowledge about health hazard is incomplete. Germ cell mutagenicity Knowledge about mutagenicity is incomplete. 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

Specific target organ toxicity -

single exposure

Knowledge about health hazard is incomplete. Knowledge about health hazard is incomplete.

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** 

The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Persistence and degradability

No data is available on the degradability of this product.

Bioaccumulative potential Mobility in soil

No data available. 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

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.

Not applicable.

# 14. Transport information

DOT

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

Transport in bulk according to

the IBC Code

Annex II of MARPOL 73/78 and

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

# 15. Regulatory information

**US** federal regulations

**General information** 

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

1071009 Version #: 04 Revision date: 09-21-2018 Issue date: 03-27-2007

# SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous Yes

chemical

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

Not regulated.

Inventory name

(SDWA)

Australia

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

Australian Inventory of Chemical Substances (AICS)

# **International Inventories**

Country(s) or region

Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	Yes
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	Yes
Korea	Existing Chemicals List (ECL)	Yes
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances	No

(PICCS)

United States & Puerto Rico Toxic Substances Control Act (TSCA) Inventory

Yes

On inventory (yes/no)\*

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

Issue date 03-27-2007 **Revision date** 09-21-2018

Version # 04

USP Reference Standards are sold for chemical test and assay purposes only, and NOT for Disclaimer

human consumption. The information contained herein is applicable solely to the chemical substance when used as a USP Reference Standard and does not necessarily relate to any other use of the substance described, (i.e. at different concentrations, in drug dosage forms, or in bulk quantities). USP Reference Standards are intended for use by persons having technical skill and at their own discretion and risk. This information has been developed by USP staff from sources considered reliable but has not been independently verified by the USP. Therefore, the USP Convention cannot guarantee the accuracy of the information in these sources nor should the statements contained herein be considered an official expression. NO REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE is made with respect to the information contained

herein.

1071009 Version #: 04 Revision date: 09-21-2018 Issue date: 03-27-2007

USP SDS US

<sup>\*</sup>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).