



## SAFETY DATA SHEET

According to CLP directive (EC) No 1272/2008

### **SECTION 1: Identification of the substance/mixture and of the company/undertaking**

- 1.1. Product identifier:** Bethanechol chloride, USP  
CAS RN # [590-63-6]  
Product Code: BTHA
- 1.2. Relevant identified uses of the substance or mixture and uses advised against**  
Identified uses: Active pharmaceutical ingredient (drug substance),  
Manufacture of drug product(s) and dosage forms  
Shall not be supply as it to the general public.
- 1.3. Details of the supplier of the safety data sheet**  
**Manufacturer:**  
**Metapharmaceutical Industrial, SL**  
Josep Plà 163 2º 5ª  
08020 Barcelona (España)  
phone: 933 089 976  
email: info@metapharmaceutical.com
- 1.4. Emergency telephone number:**  
0034 915 620 420  
Instituto Nacional de Toxicologia (Madrid, España)

### **SECTION 2: Hazards identification**

#### **2.1. Classification of the substance or mixture**

**Classification according to Regulation (EC) No 1272/2008 [EU-GHS/CLP]**

Acute toxicity, Oral (Category 4).

#### **2.2. Label elements**

Pictogram



**Signal word** Warning

**Hazard statement(s)** H302: Harmful if swallowed

#### **Precautionary statement(s)**

- Prevention (oral) P264 wash thoroughly with soap and plenty of water after handling  
P270 Do not eat, drink or smoke when using this product.
- Response (oral) P301 + P312 IF SWALLOWED: Call a doctor if you feel unwell.  
P330 Rinse mouth.
- Disposal (oral) P501 Dispose of contents/container to an approved waste disposal plant.

#### **2.3. Other hazards**

None.





## SECTION 3: Composition/information on ingredients

### 3.1. Substances

Synonyms: Carbamyl-β-methylcholine chloride

CAS #: [590-63-6]

EC Number (EINECS): 209-686-8

Chemical characterization: M.F.: C<sub>17</sub>H<sub>17</sub>ClN<sub>2</sub>O<sub>2</sub>

M.W.: 196.68 g/mol

Index No	International Chemical Identification	EC No	CAS No	Classification ATP
-	2-carbamoyloxypropyltrimethylammonium chloride ; (±)-(2-Hydroxypropyl)trimethylammonium chloride carbamate ; 1-Propanaminium, 2-[(aminocarbonyl)oxy]-N N N-trimethyl- chloride (±).	209-686-8	590-63-6	Acute Tox. 4 H302

### 3.2. Mixtures

Not applicable, pure material 100% by weight.

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

**If inhaled,** If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

**In case of skin contact,** Wash off with soap and plenty of water. Consult a physician.

**In case of eye contact,** Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

**If swallowed,** Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

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

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated. Salivation, Nausea, Vomiting, Asthma.

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

Consult a physician. Show this safety data sheet to the doctor in attendance.

## SECTION 5: Fire fighting measures

### 5.1. Extinguishing media

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

### 5.2. Precautions for fire-fighters

Wear self-contained breathing apparatus for firefighting if necessary.

### 5.3. Further information

No data available.

## SECTION 6: Accidental release measures

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

Use personal protective equipment. Avoid dust formation. Avoid breathing dust. Ensure adequate ventilation.

### 6.2. Environmental precautions

Do not let product enter drains.

### 6.3. Methods and material for containment and cleaning up

Pick up and arrange disposal without creating dust. Keep in suitable, closed containers for disposal.

### 6.4. Reference to other sections

For disposal see section 13.





## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

Avoid formation of dust and aerosols. Provide appropriate exhaust ventilation at places where dust is formed. Normal measures for preventive fire protection.

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

Store in cool place.

Keep container tightly closed in a dry and well-ventilated place.

Recommended storage temperature: 15 – 30 °C.

Store and handle in accordance with all current regulations and standards. Refer to Section 8.

### 7.3. Specific end use(s)

This substance is an active ingredient when used in the production of a drug (medicinal) product for which it is intended to be used in the manufacture.

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

Component with workplace control parameters.

### 8.2. Exposure controls

#### 8.2.1 Appropriate engineering controls

Avoid contact with skin, eyes and clothing. Wash hands before breaks and immediately after handling the product.

#### 8.2.2 Individual protection measures

Respiratory protection: Where risk assessment shows air-purifying respirators are appropriate use a dust mask type N95 (US) or type P1 (EN 143) respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Hand protection: The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it. Handle with gloves.

Eye protection: Safety glasses with side-shields conforming to EN166.

Skin and body protection: Choose body protection according to the amount and concentration of the dangerous substance at the work place.

Hygiene measures : Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

#### 8.2.3 Environmental exposure controls

No data available.

## SECTION 9: Physical and chemical properties

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

Appearance: white crystalline powder.

pH : 5.5 – 6.5 (10 mg/mL in water)

### 9.2. Other information

No data available.

## SECTION 10: Stability and reactivity

### 10.1. Chemical stability

Stable under recommended storage conditions.

### 10.2. Conditions to avoid

No data available.





## SECTION 10: Stability and reactivity (cont'd)

### 10.3. Materials to avoid

Strong oxidizing agents.

### 10.4. Hazardous decomposition products

Hazardous decomposition products formed under fire conditions. Carbon oxides, nitrogen oxides (NO<sub>x</sub>), hydrogen chloride gas.

## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects

#### a) Acute toxicity

DL50 Oral – rat – 1500 mg/kg.

#### b) Skin corrosion/irritation

No data available.

#### c) Serious eye damage/eye irritation

No data available.

#### d) Respiratory or skin sensitization

No data available.

#### e) Germ cell mutagenicity

No data available.

#### f) Carcinogenicity

No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

#### g) Reproductive toxicity

No data available.

#### h) Specific target organ toxicity – single exposure

No data available.

#### i) Specific target organ toxicity – repeated exposure

No data available.

#### j) Aspiration hazard

No data available.

### Potential health effects

Inhalation : May be harmful if inhaled. May cause respiratory tract irritation.

Ingestion : Harmful if swallowed.

Skin : May be harmful if absorbed through skin. May cause skin irritation.

Eyes : May cause eye irritation.

### Signs and symptoms of exposure

To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated, salivation, nausea, vomiting, asthma.

### Additional information

Only RTECS data are presented here, see the complete information in RTECS database (n° BR5425000).

## SECTION 12: Ecological information

### 12.1. Toxicity

No data available.

### 12.2. Persistence and degradability

No data available.





## SECTION 12: Ecological information (cont'd)

### 12.3. Bioaccumulative potential

No data available.

### 12.4. Mobility in soil

No data available.

### 12.5. Results of PBT and vPvB assessment

No data available.

### 12.6. Other adverse effects

No data available.

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

#### Product :

Observe all federal, state, and local environmental regulations. Contact a licensed professional waste disposal service to dispose of this material.

Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber.

#### Contaminated packaging

Dispose of as unused product.

## SECTION 14: Transport information

### 14.1. ADR/RID

### 14.2. IMDG

### 14.3. IATA

Please contact Seratec for transportation information.

## SECTION 15: Regulatory information

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

This substance has been elaborated in accordance with "EudraLex The Rules Governing Medicinal Products in the European Union - Volume 4; EU Guidelines to Good Manufacturing Practice Medicinal Products for Human and Veterinary Use / Part II: Basic Requirements for Active Substances used as Starting Materials". This substance is an active pharmaceutical ingredient and Article 46 (f) of Directive 2001/83/EC and Article 50 (f) of Directive 2001/82/EC; as amended by Directives 2004/27/EC and 2004/28/EC respectively, place new obligations on manufacturing authorization holders to use only active substances as per the current described substance, that have been manufactured in accordance with Good Manufacturing Practice for starting materials. Only manufacturing authorization holders are allowed to make use of this drug substance in a drug product. Other uses are for R&D purposes only, not for food or other uses.

### 15.2. Chemical safety assessment

Data not yet available.



**SECTION 16: Other information****Text of H-code(s) mentioned in Section 3**

Acute Tox.	Acute toxicity
H302	Harmful if swallowed

**Further information**

The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. The declarations are given in accordance to our current knowledge. The information has been developed by METAPHARMACEUTICAL IND, SL staff from sources considered reliable but has not been independently verified by METAPHARMACEUTICAL IND, SL. No representation or warranty, express or implied, including the warranty of merchantability and fitness for a particular purpose is made with respect to the information contained herein. METAPHARMACEUTICAL IND, SL shall not be held liable for any damage resulting from handling or from contact with the above product.

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