SAFETY DATA SHEET

SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME  
OXYBUTYNIN CHLORIDE, USP

PRODUCT CODE  
0384

SUPPLIER  
MEDISCA Inc.  
Tel.: 1.800.932.1039 | Fax.: 1.855.850.5855  
661 Route 3, Unit C, Plattsburgh, NY, 12901  
3955 W. Mesa Vista Ave., Unit A-10, Las Vegas, NV, 89118  
6641 N. Belt Line Road, Suite 130, Irving, TX, 75063

MEDISCA Pharmaceutique Inc.  
Tel.: 1.800.665.6334 | Fax.: 514.338.1693  
4509 Rue Dobrin, St. Laurent, QC, H4R 2L8  
21300 Gordon Way, Unit 153/158, Richmond, BC V6W 1M2

MEDISCA Australia PTY LTD  
Tel.: 1.300.786.392 | Fax.: 61.2.9700.9047  
Unit 7, Heritage Business Park  
5-9 Ricketty Street, Mascot, NSW 2020

EMERGENCY PHONE  
CHEMTREC Day or Night Within USA and Canada: 1-800-424-9300  
NSW Poisons Information Centre: 131 126

USES  
Anticholinergic.

SECTION 2: HAZARDS IDENTIFICATION

GHS CLASSIFICATION  
Acute Toxicity - Oral (Category 4)

PICTOGRAM  
Warning

SIGNAL WORD  
Warning

HAZARD STATEMENT(S)  
Harmful if swallowed.  
Exposure may produce an allergic reaction.

AUSTRALIA-ONLY HAZARDS  
Not Applicable.

PRECAUTIONARY STATEMENT(S)  
Prevention: Wash thoroughly after handling.  
Do not eat, drink or smoke when using this product.

Response  
IF SWALLOWED: Immediately call a poison center or medical professional. Rinse mouth.

Storage  
Not applicable.

Disposal  
Dispose of contents and/or container in accordance with local regulations.

HMIS CLASSIFICATION  
Health Hazard: 2  
Flammability: 0  
Reactivity: 0  
Personal Protection: E

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

CHEMICAL NAME  
Benzeneacetic acid, α-cyclohexyl-α-hydroxy-, 4-(diethylamino)-2-butynyl ester hydrochloride, (±)-

BOTANICAL NAME  
Not applicable

SYNONYM  
Oxybutynin hydrochloride; Ditropan; Oxibutinin hydrochloride

Last Revision: 03/2016
SAFETY DATA SHEET

CHEMICAL FORMULA: C₂₂H₃₁NO₃·HCl
CAS NUMBER: 1508-65-2
ALTERNATE CAS NUMBER: Not applicable
MOLECULAR WEIGHT: 393.95

COMPOSITION:

<table>
<thead>
<tr>
<th>CHEMICAL NAME</th>
<th>CAS NUMBER</th>
<th>% BY WEIGHT</th>
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</thead>
<tbody>
<tr>
<td>OXYBUTYNIN CHLORIDE</td>
<td>1508-65-2</td>
<td>100</td>
</tr>
</tbody>
</table>

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as health hazards and hence require reporting in this section.

NOTES:
Chemical family: Benzene derivative; Tertiary amine. Anticholinergic/Antimuscarinic.
Oxybutynin is a tertiary amine antimuscarinic. Muscarinic receptor antagonists (MRA) are a type of anticholinergic agent that block the activity of muscarinic acetylcholine receptors. It also has direct effects on smooth muscle.

SECTION 4: FIRST-AID MEASURES

IN CASE OF EYE CONTACT:
Flush with copious amounts of water for 15 minutes, separating eyelids with fingers. If irritation persists seek medical aid.

IN CASE OF SKIN CONTACT:
Wash with soap & water for 15 minutes. If irritation persists seek medical aid.

IF SWALLOWED:
Call a physician. Wash out mouth with water. Do not induce vomiting without medical advice.

IF INHALED:
Not expected to present a significant hazard under anticipated conditions of normal use.

SECTION 5: FIREFIGHTING MEASURES

SPECIFIC HAZARDS ARISING FROM THE CHEMICAL:
Not applicable

FLAMMABLE PROPERTIES:
May be combustible at high temperature

HAZARDOUS COMBUSTION PRODUCTS:
Under fire conditions, hazardous fumes will be present.

EXTINGUISHING MEDIA:
Small fire: dry chemical, CO₂ or water spray. Large fire: dry chemical, CO₂, alcohol resistant foam or water spray. Do not get water inside containers.

PROTECTIVE EQUIPMENT AND PRECAUTIONS FOR FIREFIGHTERS:
Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

SECTION 6: ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS:
Wear respiratory protection. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.

METHODS & MATERIAL FOR CONTAINMENT:
On land, sweep or shovel into suitable containers. Minimize generation of dust.
**CLEANUP PROCEDURE**

Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Wear respirator, chemical safety goggles, rubber boots and heavy rubber gloves. Stop leak if you can do it without risk. Prevent entry into waterways, sewers, basements or confined areas. Shut off all sources of ignition. Evacuate the area. If necessary, employ water fog to disperse the vapors. Absorb the matter with compatible vermiculite or other absorbing material. Place in a suitable container and retain for disposal. Ventilate and clean the affected area. Do not flush into sewerage system or to drains.

**SECTION 7: HANDLING AND STORAGE**

**PRECAUTIONS FOR SAFE HANDLING**

Do not inhale. Avoid contact with eyes, skin and clothing. Avoid prolonged or repeated exposure. Wash thoroughly after handling.

**STORAGE CONDITIONS**

Store in original container, tightly sealed, protected from direct sunlight, in a dry and well-ventilated area, away from incompatible materials. Store in accordance with local regulations. Eliminate all ignition sources. Separate from oxidizing materials. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabelled containers. Use appropriate containment to avoid environmental contamination. Recommended storage temperature: (15-30)°C, (59-86)°F. Preserve in well-closed containers. Protect from light.

**SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION**

**Chemical Name: OXYBUTYNIN CHLORIDE  CAS #: 1508-65-2**

<table>
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<tr>
<th></th>
<th>TWA</th>
<th>Ceiling</th>
<th>STEL</th>
<th>REL</th>
<th>IDLH</th>
<th>Remarks</th>
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<td>OSHA PEL</td>
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<td>N/L</td>
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<tr>
<td>NIOSH</td>
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<td>N/L</td>
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<tr>
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<td>N/L</td>
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<td>-</td>
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</tbody>
</table>

N/L = Not Listed

**EXPOSURE GUIDELINES**

Consult local authorities for provincial or state exposure limits. Particulates not otherwise regulated, respirable fraction: 5 mg/m3.

**PERSONAL PROTECTIVE EQUIPMENT**

**Eyes:** Wear appropriate protective eyeglasses or chemical safety goggles as described by WHMIS or OSHA’s eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166. **Skin:** Wear appropriate gloves to prevent skin exposure. **Respirators:** Follow WHMIS or OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced.

**SPECIFIC ENGINEERING CONTROLS**

Adequate mechanical ventilation. Fumehood, eye wash station, and safety shower.

**SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**

**PHYSICAL STATE**

Solid

**DESCRIPTION**

White, crystalline, practically odorless powder

**SOLUBILITY**

Freely soluble in water and in alcohol; very soluble in methanol and in chloroform; soluble in acetone; slightly soluble in ether; very slightly soluble in hexane.

**ODOR**

Practically odorless
### Section 10: Stability and Reactivity

<table>
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<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reactivity</td>
<td>Not established</td>
</tr>
<tr>
<td>Stability</td>
<td>Stable under recommended storage conditions</td>
</tr>
<tr>
<td>Materials to Avoid</td>
<td>Strong oxidants, bases and strong acids.</td>
</tr>
<tr>
<td>Hazardous Decomposition</td>
<td>Toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides and other gases may occur</td>
</tr>
<tr>
<td>Hazardous Polymerization</td>
<td>Will not occur</td>
</tr>
<tr>
<td>Possibility of Hazardous Reaction</td>
<td>Not established</td>
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<tr>
<td>Conditions to Avoid</td>
<td>Moisture, sunlight and extreme temperatures. Light.</td>
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</table>

### Section 11: Toxicological Information

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
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</thead>
<tbody>
<tr>
<td>Acute Toxicity</td>
<td>Oral: Rat: LD50: (mg/kg): 460</td>
</tr>
<tr>
<td></td>
<td>Dermal: Rabbit: LD50: (mg/kg): Not available</td>
</tr>
<tr>
<td></td>
<td>Inhalation: Rat: LD50: (mg/L/4hr): Not available</td>
</tr>
<tr>
<td>Skin Corrosion/Irritation</td>
<td>Due to lack of data the classification is not possible.</td>
</tr>
<tr>
<td>Serious Eye Damage/Eye Irritation</td>
<td>Due to lack of data the classification is not possible.</td>
</tr>
<tr>
<td>Respiratory or Skin Sensitization</td>
<td>Due to lack of data the classification is not possible. Exposure may produce an allergic reaction.</td>
</tr>
<tr>
<td>Germ Cell Mutagenicity</td>
<td>Due to lack of data the classification is not possible. Data from germ cell mutagenicity tests were not found. No evidence of mutagenicity has been found in studies on several test systems.</td>
</tr>
<tr>
<td>Carcinogenicity</td>
<td>OSHA: OXYBUTYNIN CHLORIDE is not listed.</td>
</tr>
<tr>
<td></td>
<td>NTP: OXYBUTYNIN CHLORIDE is not listed.</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

IARC
OXYBUTYNIN CHLORIDE is not evaluated.

California Proposition 65
This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm.

ADDITIONAL CARCINOGENICITY INFORMATION
Carcinogenicity study: Rat: 20 - 160 mg/kg/day: No evidence of carcinogenicity observed.

REPRODUCTIVE TOXICITY
Animal studies have shown reproductive toxicity with high doses of oxybutynin, hence the recommendation that it should be avoided during pregnancy; caution should also be observed during breast feeding.
Fertility study: Rat: 3 - 75 mg/kg/day: No adverse effects on fertility noted.
Reproductivity and development study: Rabbit: 48 mg/kg/day: Maternal toxicity but no adverse effects on reproductivity or offspring development.
Reproductivity and development study: Rat: 75 - 100 mg/kg/day: Skeletal malformations in the offspring at maternally toxic doses.
Reproductivity and development study: Rat: Increase in ventricular septal defects seen with administration of very high, maternally toxic doses during gestation.
Based on available data, the classification criteria are not met.

SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE
Based on available data, the classification criteria are not met.

SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE
Based on available data, the classification criteria are not met.

ASPIRATION HAZARDS
Based on available data, the classification criteria are not met.

SIGNS AND SYMPTOMS OF EXPOSURE
Not expected to present a significant hazard under anticipated conditions of normal use.


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. Causes skin irritation.
Eyes: May cause eye irritation.

SECTION 12: ECOLOGICAL INFORMATION

TOXICITY
EC50: 48 Hr: Daphnia magna: (mg/L): Not available
LC50: 96 Hr: Fish: (mg/L): Not available
IC50: 72 Hr: Algae: (mg/L): Not available

PERSISTENCE AND DEGRADABILITY
Not available

BIOACCUMULATIVE POTENTIAL
Log Pow: 2.9.

MOBILITY IN SOIL
Not available

OTHER ADVERSE EFFECTS
This product is not intended to be released into the environment.
SAFETY DATA SHEET

SECTION 13: DISPOSAL CONSIDERATIONS

WASTE DISPOSAL
Dispose of in accordance with federal / local laws and regulations. Avoid release into the environment.

SECTION 14: TRANSPORT INFORMATION

UNITED STATES & CANADA
- UN PROPER SHIPPING NAME: Not dangerous good
- UN NUMBER: Not applicable
- CLASS: Not applicable
- PACKING GROUP: Not applicable

AUSTRALIA
- UN PROPER SHIPPING NAME: Not dangerous good
- UN NUMBER: Not applicable
- CLASS: Not applicable
- PACKING GROUP: Not applicable

ENVIRONMENTAL HAZARDS: Not available

SPECIAL SHIPPING INFORMATION: Not applicable

SECTION 15: REGULATORY INFORMATION

<table>
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<th></th>
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<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
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</table>

N/L = Not Listed; X = Listed

AUSTRALIAN REGULATIONS

<table>
<thead>
<tr>
<th>Chemical Name &amp; CAS</th>
<th>Poisons and Therapeutic Goods Regulation</th>
<th>Therapeutic Goods Act</th>
<th>Code of Practices - Illicit Drug Precursors</th>
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</thead>
<tbody>
<tr>
<td>OXYBUTYNIN CHLORIDE 1508-65-2</td>
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</tbody>
</table>

SECTION 16: OTHER INFORMATION

REFERENCES
Available upon request

Last Revision: 03/2016
ABBRICATIONS AND ACRONYMS

CAS – Chemical Abstract Service; GHS – Global Harmonized System; OSHA PEL – Occupational Safety & Health Administration Permissible Exposure Limits; TWA – Time Weighted Average; HSIS – Hazardous Substances Information System; STEL – Short Term Exposure Limit; AIHA WEEL – American Industrial Hygiene Association Workplace Environment Exposure Levels; LD50 – Lethal Dose, 50%; IARC – International Agency for Research on Cancer; NTP – National Toxicology Program; WHMIS – Workplace Hazardous Materials Information System; SARA – Superfund Amendments and Reauthorization Act; EPA – Environmental Protection Agency; CERCLA – Comprehensive Environmental Response, Compensation, and Liability Act; HMIS – Hazardous Materials Information System; NIOSH – National Institute for Occupational Safety and Health; MSHA – Mine Safety and Health Administration; ACGIH – American Conference of Governmental Industrial Hygienists; IDHL – Immediately Dangerous to Health or Life; TLV – Threshold Limit Value; HSE – Health and Safety Executive; REL – Recommended Exposure Limit

LAST REVISION

03/2016

SUPERSEDES

08/2013

DISCLAIMER

This document was created in accordance with OSHA, Safe Work Australia and WHMIS regulations. 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 information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. MEDISCA® shall not be held liable for any damage resulting from handling or from contact with the above product. Recipients of the product must take responsibility for observing existing laws and regulations.