



# SAFETY DATA SHEET

Revision Date 02-Oct-2018

Version 11

## 1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

### Product identifier

**Product Name** OXYBUT HCL 100MG/G MIX

### Other means of identification

**Product Code** 175547

**Synonyms** Ditropan, Gelnique, Oxytrol

### Recommended use of the chemical and restrictions on use

**Recommended Use** Overactive Bladder

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.

### Details of the supplier of the safety data sheet

#### **Manufacturer**

Allergan plc  
5 Giralda Farms  
Madison, NJ USA 07940  
+1-800-272-5525

**E-mail address** SDS@Allergan.com

### Emergency telephone number

**Emergency Telephone** Call CHEMTREC Day or Night  
Within USA or Canada: 1-800-424-9300  
Outside USA and Canada: +1-703-741-5970 (collect calls accepted)

## 2. HAZARDS IDENTIFICATION

### Classification

#### **OSHA Regulatory Status**

This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Serious eye damage/eye irritation	Category 2A
Respiratory sensitization	Category 1
Skin sensitization	Category 1
Carcinogenicity	Category 1A

### Label elements

#### **Emergency Overview**

**Danger**

#### **Hazard statements**

H317 - May cause an allergic skin reaction  
H319 - Causes serious eye irritation  
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled  
H350 - May cause cancer



**Appearance** No information available      **Physical state** No information available      **Odor** No information available

**Chemical Name**  
OXYBUTYNIN CL/HCL USP

**Symptoms**

Urinary Retention: Use caution in patients with clinically significant bladder outflow obstruction because of the risk of urinary retention. Gastrointestinal Disorders: Use caution in patients with gastrointestinal obstructive disorders or decreased intestinal motility because of the risk of gastric retention. Use caution in patients with gastroesophageal reflux and/or those taking drugs that can cause or exacerbate esophagitis. Angioedema: Angioedema has been reported with oral oxybutynin use. If symptoms of angioedema occur, discontinue product and initiate appropriate therapy. Skin Hypersensitivity: Discontinue product in patients with skin hypersensitivity. Central Nervous System Effects: Somnolence has been reported with product. Advise patients not to drive or operate heavy machinery until they know how product affects them. Skin Transference: Advise patients to cover the application site with clothing if skin-to-skin contact at the application site is anticipated. Wash hands immediately after product application. Flammable Gel: Contains alcohol-based gel. Avoid open fire or smoking until the gel has dried.

**Chemical Name**  
OXYBUTYNIN CL/HCL USP

**Medical Conditions Aggravated by Exposure**

The most common adverse reactions were dry mouth, urinary tract infection, and application site reactions.

**Precautionary statements**

P264 - Wash face, hands and any exposed skin thoroughly after handling  
 P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing  
 P337 + P313 - If eye irritation persists: Get medical advice/attention  
 P285 - In case of inadequate ventilation wear respiratory protection  
 P304 + P341 - IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing  
 P342 + P311 - If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician  
 P261 - Avoid breathing dust/fume/gas/mist/vapors/spray  
 P272 - Contaminated work clothing should not be allowed out of the workplace  
 P302 + P352 - IF ON SKIN: Wash with plenty of soap and water  
 P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention  
 P321 - Specific treatment (see supplemental first aid instructions on this label)  
 P363 - Wash contaminated clothing before reuse  
 P201 - Obtain special instructions before use  
 P202 - Do not handle until all safety precautions have been read and understood  
 P281 - Use personal protective equipment as required  
 P308 + P313 - IF exposed or concerned: Get medical advice/attention  
 P405 - Store locked up  
 P501 - Dispose of contents/ container to an approved waste disposal plant  
 P280 - Wear protective gloves/protective clothing/eye protection/face protection

**Other Information**

Over the counter drugs in their solid form are considered exempt under the criteria of the Federal OSHA Hazard Communication Standard 20 CFR 1910.1200. However, in an industrial setting where a component's occupational exposure limit may be surpassed, than can be considered hazardous

**3. COMPOSITION/INFORMATION ON INGREDIENTS**

Chemical Name	CAS No.	EINECS	Weight-%
ALCOHOL USP	64-17-5	200-578-6	60 - 100*
PURIFIED WATER USP	7732-18-5	231-791-2	10 - 30*
OXYBUTYNIN CL/HCL USP	1508-65-2	216-139-7	7 - 13*
HYDROXYPROPYL CELL KLUCEL EF	9004-64-2	N/A	1 - 5*
GLYCERINE USP (96%)	56-81-5	200-289-5	1 - 5*

\*The exact percentage (concentration) of composition has been withheld as a trade secret.

#### 4. FIRST AID MEASURES

##### First aid measures

<b>Eye contact</b>	Rinse immediately with plenty of water and seek medical advice.
<b>Skin Contact</b>	Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes.
<b>Inhalation</b>	Remove to fresh air.
<b>Ingestion</b>	Consult a physician if necessary.

#### 5. FIRE-FIGHTING MEASURES

##### Suitable extinguishing media

Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

##### Unsuitable extinguishing media

None known.

##### Specific hazards arising from the chemical

Fire may produce irritating, corrosive and/or toxic gases.

##### Explosion data

<b>Sensitivity to Mechanical Impact</b>	Not impact sensitive.
<b>Sensitivity to Static Discharge</b>	Fine dust dispersed in air, in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.

##### Protective equipment and precautions for firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

#### 6. ACCIDENTAL RELEASE MEASURES

<b>Personal precautions</b>	Use personal protection recommended in Section 8. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing.
<b>Environmental precautions</b>	Do not allow into any sewer, on the ground or into any body of water.
<b>Methods for containment</b>	Prevent further leakage or spillage if safe to do so.
<b>Methods for cleaning up</b>	Avoid creating dust.

#### 7. HANDLING AND STORAGE

<b>Advice on safe handling</b>	Avoid contact with skin, eyes or clothing. Avoid generation of dust. Do not eat, drink or smoke when using this product.
<b>Storage Conditions</b>	Keep containers tightly closed in a dry, cool and well-ventilated place. Store away from incompatible materials.

**Incompatible materials** None known based on information supplied.

**8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

**Control parameters**

**Exposure Guidelines**

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH IDLH	Allergan OEL (ug/m <sup>3</sup> )
ALCOHOL USP 64-17-5	STEL: 1000 ppm	TWA: 1000 ppm TWA: 1900 mg/m <sup>3</sup> (vacated) TWA: 1000 ppm (vacated) TWA: 1900 mg/m <sup>3</sup>	IDLH: 3300 ppm TWA: 1000 ppm TWA: 1900 mg/m <sup>3</sup>	N/A
OXYBUTYNIN CL/HCL USP 1508-65-2	N/A	N/A	N/A	10
GLYCERINE USP (96%) 56-81-5	N/A	TWA: 15 mg/m <sup>3</sup> mist, total particulate TWA: 5 mg/m <sup>3</sup> mist, respirable fraction (vacated) TWA: 10 mg/m <sup>3</sup> mist, total particulate (vacated) TWA: 5 mg/m <sup>3</sup> mist, respirable fraction	N/A	N/A

NIOSH IDLH *Immediately Dangerous to Life or Health*

**Other Information** Vacated limits revoked by the Court of Appeals decision in AFL-CIO v. OSHA, 965 F.2d 962 (11th Cir., 1992).

**Appropriate engineering controls**

**Engineering Controls**

The health hazard risks of handling this material are dependent on factors, such as physical form and quantity. Site specific risk assessments should be conducted to determine the appropriate exposure control measures. Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels as low as reasonably achievable.

**Individual protection measures, such as personal protective equipment**

**Eye/face protection**

No eye protection is normally needed during medical administration of this product. During operations in which dusts of the product may be generated, safety glasses should be considered.

**Skin and body protection**

During medical administration of this product, medical latex or nitrile gloves should be worn to avoid absorption of the product. Use appropriate protective clothing for the task (e.g., lab coat, etc.).

**Respiratory protection**

Respiratory protection is generally not needed during routine conditions of use of this product. If respiratory protection is needed, use only respiratory protection authorized under appropriate regional regulations.

**9. PHYSICAL AND CHEMICAL PROPERTIES**

**Information on basic physical and chemical properties**

<b>Physical state</b>	No information available	<b>Appearance</b>	No information available
<b>Color</b>	No information available	<b>Odor</b>	No information available
<b>Odor threshold</b>	No information available		

**Property**

pH

**Values**

No information available

Melting point/freezing point	No information available
Boiling point / boiling range	No information available
Flash point	No information available
Evaporation rate	No information available
Flammability (solid, gas)	No information available
Flammability Limit in Air	
Upper flammability limit:	No information available
Lower flammability limit:	No information available
Vapor pressure	No information available
Vapor density	No information available
Specific Gravity	No information available
Water solubility	No information available
Solubility in other solvents	No information available
Partition coefficient	No information available
Autoignition temperature	No information available
Decomposition temperature	No information available
Explosive properties	No information available
Oxidizing properties	No information available

**Other Information**

Molecular weight	No information available
VOC Content (%)	No information available
Density	No information available
Bulk density	No information available

## 10. STABILITY AND REACTIVITY

**Reactivity**

Not defined As Reactive substance

**Chemical stability**

Stable under normal conditions.

**Possibility of Hazardous Reactions**

None under normal processing.

**Conditions to avoid**

Aerosol formation.

**Incompatible materials**

None known based on information supplied.

**Hazardous Decomposition Products**

None known based on information supplied.

## 11. TOXICOLOGICAL INFORMATION

**Information on likely routes of exposure****Acute toxicity**

Chemical Name	Inhalation	Eye contact	Skin Contact	Ingestion
ALCOHOL USP	Avoid breathing vapors or mists.	See Symptoms for more information.	Avoid contact with skin.	See Symptoms for more information.

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
ALCOHOL USP	= 7060 mg/kg ( Rat )	N/A	= 124.7 mg/L ( Rat ) 4 h
PURIFIED WATER USP	> 90 mL/kg ( Rat )	N/A	N/A
OXYBUTYNIN CL/HCL USP	6433.1 mg/kg (rat)	N/A	N/A
HYDROXYPROPYL CELL KLUCEL EF	= 10200 mg/kg ( Rat )	N/A	N/A
GLYCERINE USP (96%)	= 12600 mg/kg ( Rat )	> 10 g/kg ( Rabbit )	> 570 mg/m <sup>3</sup> ( Rat ) 1 h

**Delayed and immediate effects as well as chronic effects from short and long-term exposure**

Chemical Name	Germ cell mutagenicity	Carcinogenicity	Reproductive toxicity	Effects on or via lactation
ALCOHOL USP	Not mutagenic in the standard battery of tests.	This product is categorized as a Group I by the IARC because of the major metabolite of ethanol, acetaldehyde is carcinogenic in experimental animals.	Studies have shown developmental toxicity, but only at high doses.	No information available
OXYBUTYNIN CL/HCL USP	Not Suspected of being a Mutagen.	Not suspected of being a human carcinogen.	Not suspected of being a reproductive hazard.	It is not known whether this drug is excreted in human milk. Because most drugs are excreted in human milk, if use of this drug is deemed essential, the patient should stop nursing.
GLYCERINE USP (96%)	Not mutagenic in the standard battery of tests.	This product does not contain any carcinogens or potential carcinogens as listed by OSHA, IARC or NTP.	This product does not contain any known or suspected reproductive hazards.	It is not known whether the drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when this drug is administered to nursing mothers.

#### Numerical measures of toxicity - Product Information

The following values are calculated based on chapter 3.1 of the GHS document .

ATEmix (oral) 8188 mg/kg  
ATEmix (inhalation-dust/mist) 13.1 mg/l

## 12. ECOLOGICAL INFORMATION

#### Ecotoxicity

12% of the mixture consists of component(s) of unknown hazards to the aquatic environment

Chemical Name	Algae/aquatic plants	Fish	Crustacea
ALCOHOL USP 64-17-5	N/A	100: 96 h Pimephales promelas mg/L LC50 static 13400 - 15100: 96 h Pimephales promelas mg/L LC50 flow-through 12.0 - 16.0: 96 h Oncorhynchus mykiss mL/L LC50 static	9268 - 14221: 48 h Daphnia magna mg/L LC50 10800: 24 h Daphnia magna mg/L EC50 2: 48 h Daphnia magna mg/L EC50 Static
GLYCERINE USP (96%) 56-81-5	N/A	51 - 57: 96 h Oncorhynchus mykiss mL/L LC50 static	500: 24 h Daphnia magna mg/L EC50

Chemical Name	Persistence and degradability	Bioaccumulation	Mobility	Partition coefficient
ALCOHOL USP 64-17-5	N/A	N/A	N/A	-0.32
GLYCERINE USP (96%) 56-81-5	N/A	N/A	N/A	-1.76

Other adverse effects No information available

## 13. DISPOSAL CONSIDERATIONS

#### Waste treatment methods

**Disposal of wastes** Disposal should be in accordance with applicable regional, national and local laws and regulations.

**Contaminated packaging** Do not reuse container. Dispose of contents/containers in accordance with local regulations.

This product contains one or more substances that are listed with the State of California as a hazardous waste.

Chemical Name	California Hazardous Waste Status
ALCOHOL USP 64-17-5	Toxic Ignitable

**14. TRANSPORT INFORMATION**

<b>DOT</b>	Not regulated
<b>TDG</b>	Not regulated
<b>ICAO (air)</b>	Not regulated
<b>IATA</b>	Not regulated
<b>IMDG</b>	Not regulated
<b>ADR</b>	Not regulated
<b>ADN</b>	Not regulated

**15. REGULATORY INFORMATION**

**International Inventories**

<b>TSCA</b>	Not Listed
<b>DSL/NDSL</b>	Not Listed
<b>EINECS/ELINCS</b>	Not Listed

**Legend:**

**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory  
**DSL/NDSL** - Canadian Domestic Substances List/Non-Domestic Substances List  
**EINECS/ELINCS** - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

**US Federal Regulations**

**Carcinogenicity** The table below indicates whether each agency has listed any ingredient as a carcinogen. This product contains one or more substances which are classified by IARC as carcinogenic to humans (Group I), probably carcinogenic to humans (Group 2A) or possibly carcinogenic to humans (Group 2B)

Chemical Name	ACGIH	IARC	NTP	OSHA
ALCOHOL USP 64-17-5	A3	Group 1	Known	X

**SARA 313**

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372

**SARA 311/312 Hazard Categories**

<b>Acute health hazard</b>	No
<b>Chronic Health Hazard</b>	No
<b>Fire hazard</b>	No
<b>Sudden release of pressure hazard</b>	No
<b>Reactive Hazard</b>	No

**CWA (Clean Water Act)**

This product contains the following substances which are regulated pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42)

**CERCLA**

This material, as supplied, contains one or more substances regulated as a hazardous substance under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302)

### US State Regulations

#### **California Proposition 65**

This product contains the following Proposition 65 chemicals

Chemical Name	California Proposition 65
ALCOHOL USP - 64-17-5	Carcinogen Developmental

#### **U.S. State Right-to-Know Regulations**

Chemical Name	New Jersey	Massachusetts	Pennsylvania
ALCOHOL USP 64-17-5	X	X	X
PURIFIED WATER USP 7732-18-5	-	-	X
GLYCERINE USP (96%) 56-81-5	X	X	X
SODIUM HYDROX 1.0N SOLN 1310-73-2	X	X	X

### 16. OTHER INFORMATION

**Revision Date** 02-Oct-2018  
**Revision Note** No information available

#### **Disclaimer**

The information provided in this Material Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

**End of Safety Data Sheet**