SAFETY DATA SHEET

Revision Date 02-Oct-2018

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)

<table>
<thead>
<tr>
<th>Serious eye damage/eye irritation</th>
<th>Category 2A</th>
</tr>
</thead>
<tbody>
<tr>
<td>Respiratory sensitization</td>
<td>Category 1</td>
</tr>
<tr>
<td>Skin sensitization</td>
<td>Category 1</td>
</tr>
<tr>
<td>Carcinogenicity</td>
<td>Category 1A</td>
</tr>
</tbody>
</table>

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
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
### 4. FIRST AID MEASURES

**First aid measures**

**Eye contact**
Rinse immediately with plenty of water and seek medical advice.

**Skin Contact**
Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes.

**Inhalation**
Remove to fresh air.

**Ingestion**
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**
- **Sensitivity to Mechanical Impact**: Not impact sensitive.
- **Sensitivity to Static Discharge**: 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

**Personal precautions**
Use personal protection recommended in Section 8. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing.

**Environmental precautions**
Do not allow into any sewer, on the ground or into any body of water.

**Methods for containment**
Prevent further leakage or spillage if safe to do so.

**Methods for cleaning up**
Avoid creating dust.

### 7. HANDLING AND STORAGE

**Advice on safe handling**
Avoid contact with skin, eyes or clothing. Avoid generation of dust. Do not eat, drink or smoke when using this product.

**Storage Conditions**
Keep containers tightly closed in a dry, cool and well-ventilated place. Store away from incompatible materials.

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**Chemical Name**

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

*The exact percentage (concentration) of composition has been withheld as a trade secret.*
8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Exposure Guidelines

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>ACGIH TLV</th>
<th>OSHA PEL</th>
<th>NIOSH IDLH</th>
<th>Allergen OEL (ug/m³)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALCOHOL USP 64-17-5</td>
<td>STEL: 1000 ppm TWA: 1000 ppm TWA: 1900 mg/m³ (vacated) TWA: 1000 ppm TWA: 1900 mg/m³</td>
<td>N/A</td>
<td>IDLH: 3300 ppm TWA: 1000 ppm TWA: 1900 mg/m³</td>
<td>N/A</td>
</tr>
<tr>
<td>OXYBUTYNIN CL/HCL USP 1508-65-2</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>10</td>
</tr>
<tr>
<td>GLYCERINE USP (96%) 56-81-5</td>
<td>N/A</td>
<td>TWA: 15 mg/m³ mist, total particulate TWA: 5 mg/m³ mist, respirable fraction (vacated) TWA: 10 mg/m³ mist, total particulate (vacated) TWA: 5 mg/m³ mist, respirable fraction</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Property</th>
<th>Values</th>
<th>Property</th>
<th>Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical state</td>
<td>No information available</td>
<td>Appearance</td>
<td>No information available</td>
</tr>
<tr>
<td>Color</td>
<td>No information available</td>
<td>Odor</td>
<td>No information available</td>
</tr>
<tr>
<td>Odor threshold</td>
<td>No information available</td>
<td></td>
<td></td>
</tr>
<tr>
<td>pH</td>
<td>No information available</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Inhalation</th>
<th>Eye contact</th>
<th>Skin Contact</th>
<th>Ingestion</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALCOHOL USP</td>
<td>Avoid breathing vapor or mist.</td>
<td>See Symptoms for more information.</td>
<td>Avoid contact with skin.</td>
<td>See Symptoms for more information.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Oral LD50</th>
<th>Dermal LD50</th>
<th>Inhalation LC50</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALCOHOL USP</td>
<td>= 7060 mg/kg (Rat)</td>
<td>N/A</td>
<td>= 124.7 mg/L (Rat) 4 h</td>
</tr>
<tr>
<td>PURIFIED WATER USP</td>
<td>&gt; 90 mL/kg (Rat)</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>OXYBUTYNIN CL/HCL USP</td>
<td>6433.1 mg/kg (rat)</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>HYDROXYPROPYL CELL KLUCEL EF</td>
<td>= 10200 mg/kg (Rat)</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>GLYCERINE USP (96%)</td>
<td>= 12600 mg/kg (Rat)</td>
<td>&gt; 10 g/kg (Rabbit)</td>
<td>&gt; 570 mg/m³ (Rat) 1 h</td>
</tr>
</tbody>
</table>

Delayed and immediate effects as well as chronic effects from short and long-term exposure
<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Germ cell mutagenicity</th>
<th>Carcinogenicity</th>
<th>Reproductive toxicity</th>
<th>Effects on or via lactation</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALCOHOL USP</td>
<td>Not mutagenic in the standard battery of tests.</td>
<td>This product is categorized as a Group I by the IARC because of the major metabolite of ethanol, acetaldehyde is carcinogenic in experimental animals.</td>
<td>Studies have shown developmental toxicity, but only at high doses.</td>
<td>No information available</td>
</tr>
<tr>
<td>OXYBUTYNIN CL/HCL USP</td>
<td>Not Suspected of being a Mutagen.</td>
<td>Not suspected of being a human carcinogen.</td>
<td>Not suspected of being a reproductive hazard.</td>
<td>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.</td>
</tr>
<tr>
<td>GLYCERINE USP (96%)</td>
<td>Not mutagenic in the standard battery of tests.</td>
<td>This product does not contain any carcinogens or potential carcinogens as listed by OSHA, IARC or NTP.</td>
<td>This product does not contain any known or suspected reproductive hazards.</td>
<td>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.</td>
</tr>
</tbody>
</table>

### Numerical measures of toxicity - Product Information

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

<table>
<thead>
<tr>
<th>ATEmix (oral)</th>
<th>8188 mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>ATEmix (inhalation-dust/mist)</td>
<td>13.1 mg/l</td>
</tr>
</tbody>
</table>

### 12. ECOLOGICAL INFORMATION

#### Ecotoxicity

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

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Algae/aquatic plants</th>
<th>Fish</th>
<th>Crustacea</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALCOHOL USP 64-17-5</td>
<td>N/A</td>
<td>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</td>
<td>9268 - 14221: 48 h Daphnia magna mg/L EC50 10800: 24 h Daphnia magna mg/L EC50 2: 48 h Daphnia magna mg/L EC50 Static</td>
</tr>
<tr>
<td>GLYCERINE USP (96%) 56-81-5</td>
<td>N/A</td>
<td>51 - 57: 96 h Oncorhynchus mykiss mL/L LC50 static</td>
<td>500: 24 h Daphnia magna mg/L EC50</td>
</tr>
</tbody>
</table>

#### 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.

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>California Hazardous Waste Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALCOHOL USP</td>
<td>Toxic Ignitable</td>
</tr>
<tr>
<td>64-17-5</td>
<td></td>
</tr>
</tbody>
</table>

### 14. TRANSPORT INFORMATION

**DOT**
- Not regulated

**TDG**
- Not regulated

**ICAO (air)**
- Not regulated

**IATA**
- Not regulated

**IMDG**
- Not regulated

**ADR**
- Not regulated

**ADN**
- Not regulated

### 15. REGULATORY INFORMATION

#### International Inventories

<table>
<thead>
<tr>
<th>TSCA</th>
<th>Not Listed</th>
</tr>
</thead>
<tbody>
<tr>
<td>DSL/NDSL</td>
<td>Not Listed</td>
</tr>
<tr>
<td>EINECS/ELINCS</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

**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)

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>ACGIH</th>
<th>IARC</th>
<th>NTP</th>
<th>OSHA</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALCOHOL USP</td>
<td>A3</td>
<td>Group 1</td>
<td>Known</td>
<td>X</td>
</tr>
<tr>
<td>64-17-5</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**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**

- Acute health hazard: No
- Chronic Health Hazard: No
- Fire hazard: No
- Sudden release of pressure hazard: No
- Reactive Hazard: 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

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>California Proposition 65</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALCOHOL USP - 64-17-5</td>
<td>Carcinogen</td>
</tr>
<tr>
<td></td>
<td>Developmental</td>
</tr>
</tbody>
</table>

U.S. State Right-to-Know Regulations

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>New Jersey</th>
<th>Massachusetts</th>
<th>Pennsylvania</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALCOHOL USP 64-17-5</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>PURIFIED WATER USP 7732-18-5</td>
<td>-</td>
<td>-</td>
<td>X</td>
</tr>
<tr>
<td>GLYCERINE USP (96%) 56-81-5</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>SODIUM HYDROX 1.0N SOLN 1310-73-2</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>

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