



SAFETY DATA SHEET

Prepared to U.S. OSHA, CMA, ANSI, Canadian WHMIS Standards, European Union CLP EC 1272/2008 and the Global Harmonization Standard

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY UNDERTAKING

TRADE/MATERIAL NAME: OXYTROL Oxybutynin Transdermal System

DESCRIPTION: Oxytrol Patch
OTHER DESIGNATIONS: NDC #: 0023-6153-08
CHEMICAL NAME: D,L(racemic)-4-Diethylamino-2-butynyl Phenylcyclohexylglycolate
CHEMICAL FAMILY: Anticholinergic
HOW SUPPLIED: Transdermal Patch
FORMULA: C₂₂H₃₁NO₃

PRODUCT USE:	Pharmaceutical for Human Use
SUPPLIER/MANUFACTURER'S NAME:	ALLERGAN
ADDRESS:	5 Giralda Farms Madison, NJ 07940
BUSINESS PHONE/GENERAL MSDS INFORMATION:	1-800-272-5525
EMERGENCY PHONE (U.S./NORTH AMERICA):	CHEMTREC: 1-800-424-9300 (24 hrs)
EMERGENCY PHONE (OUTSIDE U.S.):	CHEMTREC: 1-703-527-3887 (24 hrs)
Email:	SafetyDataSheets@Allergan.com

NOTE: ALL United States Occupational Safety and Health Administration Standard (29 CFR 1910.1200), U.S. State equivalent Standards, Canadian WHMIS [Controlled Products Regulations], EU Directives through EC 1907: 2006, and European Union CLP EC 1272/2008, required information is included in appropriate sections based on the U.S. ANSI Z400.1-2010 format. This product has been classified in accordance with the hazard criteria of the countries listed above.

DATE OF PREPARATION: October 30, 2018

DATE OF REVISION:

2. HAZARD IDENTIFICATION

EU CLP REGULATION (EC) 1272/2008 LABELING AND CLASSIFICATION: According to Article 1, item 5 (a) of CLP Regulation (EC) 1272/2008, medicinal products in the finished state for human use, as defined in 2001/83/EC, are exempted from classification and other criteria of 1272/2008.

Classification: Not Applicable Signal Word: Not Applicable Hazard Statement Codes: Not Applicable

EU LABELING AND CLASSIFICATION 67/548/EEC: According to Article 1 of European Union Council Directive 92/32/EEC, medical products in the finished state for human use (as defined by European Union Council Directives 67/548/EEC and 87/21/EEC) are not subject to the regulations and administrative provisions of European Union Council Directive 92/32/EEC.

Classification: Not Applicable Risk Phrases: Not Applicable Safety Phrases: Not Applicable

See Section 16 for full EU classification information of product and components and full text of hazard and precautionary statements.

EMERGENCY OVERVIEW:

Product Description: This product is a translucent laminate patch with adhesive on one side, packaged in a foil-backed pouch. The raw chemical ingredients are mixed with the Duro-Tak® Adhesive solution, which is then applied to the patch. Although the raw adhesive contains a copolymer, isopropyl alcohol and ethyl acetate, these volatile compounds are removed in the manufacturing process and only trace amounts remain in the final product.

Health Hazards: The chief health hazard associated with overexposures during normal use and handling is irritation of contaminated skin. Individuals who have had allergic reactions to products containing Oxybutynin or any of the other ingredients in this product may experience allergic reactions to this product. Therapeutic use of Oxybutynin can cause adverse symptoms of the eyes, gastrointestinal system, cardiovascular system, central nervous system, and skin.



Reactivity Hazards: This product is not reactive.

Flammability Hazards: If heated to high temperatures for a prolonged period, the product may ignite. When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds (including carbon oxides and nitrogen oxides).

Environmental Hazards: Large quantities released to the aquatic and terrestrial environment may have an adverse effect.

Emergency Considerations: Emergency responders should wear appropriate protection for situation to which they respond.

3. COMPOSITION and INFORMATION ON INGREDIENTS

CHEMICAL NAME	CAS #	EINECS #	% w/w	EU Classification (67/548/EEC) GHS & EU Classification (1272/2008 EC) Risk Phrases/Hazard Statements/Symbol
Oxybutynin	5633-20-5	Unlisted	Proprietary	SELF-CLASSIFICATION: EU (67/548/EEC): Classification: Harmful; Toxic Risk Phrases: R22; R48  Symbol: EU/GHS 1272/2008: Signal Word: Warning Classification: Acute Oral Toxicity Cat. 4; Target Organ toxicity, repeated exposure, Cat. 2 Hazard Statement Codes: H302; H373  Hazard Symbols/Pictograms:
Triacetin	102-76-1	203-051-9	Proprietary	EU 67/548 Hazard Classification: Not Applicable EU/GHS 1272/2008 Classification: Not Applicable
Duro-Tak® Acrylic Copolymer Adhesive	Mixture	Mixture	Balance	EU 67/548 Hazard Classification: Not Applicable EU/GHS 1272/2008 Classification: Not Applicable

See Section 16 for full EU classification information of product and components.

4 FIRST-AID MEASURES

Persons developing hypersensitivity reactions should receive medical attention. Remove patch immediately. If breathing is difficult, give oxygen. If not breathing, give artificial respiration. Take a copy of label and MSDS to physician or health professional with the contaminated individual.

SKIN EXPOSURE: If adverse skin effects occur, remove patch and rinse affected area with soap and water. Seek medical attention.

EYE EXPOSURE: If components from the patch contaminate the eyes, open eyes under gently running water. Use sufficient force to open eyelids and then "roll" while flushing eyes. Minimum flushing is for 15 minutes if the exposure has resulted in an adverse effect. The contaminated individual must seek medical attention if any adverse effect continues after rinsing.

INHALATION: Not a possible route of exposure to components of this product due to its form.

INGESTION: If this product is swallowed, CALL PHYSICIAN OR POISON CONTROL CENTER FOR MOST CURRENT INFORMATION. If professional advice is not available, do not induce vomiting. Never induce vomiting or give diluents (milk or water) to someone who is unconscious, having convulsions, or unable to swallow. If victim is convulsing, maintain an open airway and obtain immediate medical attention.

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: Pre-existing skin conditions, cardiovascular conditions, and central nervous system conditions may be aggravated by repeated overexposures to this product.

RECOMMENDATIONS TO PHYSICIANS: This product should only be given to patients by persons experienced in management of patients receiving the type of therapy intended for this product. If there are signs of overdosage, the patch should be removed immediately. The skin may be washed with water only, as soap may facilitate absorption. Owing to a depot of Oxybutynin in the skin, delivery of Oxybutynin to the bloodstream will continue for several hours afterward. Monitor until symptoms resolve.

5. FIRE-FIGHTING MEASURES

FLASH POINT: Not established.

AUTOIGNITION TEMPERATURE: Not established.

FLAMMABLE LIMITS (in air by volume, %):

Lower (LEL): Not applicable.

Upper (UEL): Not applicable.

FIRE EXTINGUISHING MATERIALS: Use extinguishing media appropriate for surrounding fire.

Water Spray: OK Carbon Dioxide: OK

Foam: OK Dry Chemical: OK

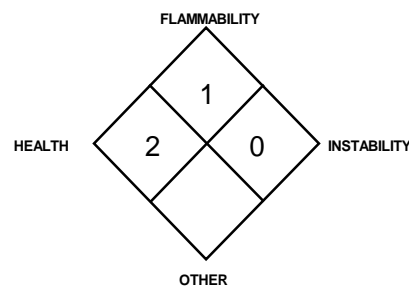
Halon: OK Other: Any "ABC" Class

UNUSUAL FIRE AND EXPLOSION HAZARDS: This product may ignite if highly heated for a prolonged period of time. This product may contribute to the intensity of a fire, especially if large quantities of the product are involved. When involved in a fire, the products of thermal decomposition may include irritating fumes and toxic gases (e.g., carbon oxides and nitrogen oxides).

Explosion Sensitivity to Mechanical Impact: Not sensitive.

Explosion Sensitivity to Static Discharge: Not sensitive.

NFPA RATING



Hazard Scale: 0 = Minimal 1 = Slight
2 = Moderate 3 = Serious 4 = Severe

5. FIRE-FIGHTING MEASURES (Continued)

SPECIAL FIRE-FIGHTING PROCEDURES: Incipient fire responders should wear eye protection. Structural firefighters must wear Self-Contained Breathing Apparatus (SCBA) and full protective equipment. If protective equipment is contaminated by this product, it should be thoroughly washed with running water prior to removal of SCBA respiratory protection. Firefighters whose protective equipment becomes contaminated should thoroughly shower with warm, soapy water and should receive medical evaluation if they experience any adverse effects.

6. ACCIDENTAL RELEASE MEASURES

SPILL RESPONSE: Sweep up spilled patches and wipe area with damp sponge or polypad. Place all spill residue in an appropriate container and seal. Dispose of in accordance with appropriate U.S. Federal, State, and local regulations or with regulations of the EU and its member states or Canada and its Provinces.

7. HANDLING and USE

WORK PRACTICES AND HYGIENE PRACTICES: As with all chemicals, avoid getting this product ON YOU or IN YOU. Do not eat, drink, smoke, or apply cosmetics while handling this product. Wash hands thoroughly after handling this product or equipment and containers that contain this product. Follow SPECIFIC USE INSTRUCTIONS supplied with this product. Particular care in working with this product must be practiced in pharmacies and other preparation areas, during manufacture of this compound, and during patient administration.

STORAGE AND HANDLING PRACTICES: Employees must be trained to properly use this product. Use of this product should be performed in a designated area for working with drugs. Ensure product is properly labeled. Store this product away from incompatible materials. Store this product in original container. Store product at room temperature (15–30°C [59–86°F]).

PRODUCT PREPARATION INSTRUCTIONS FOR MEDICAL PERSONNEL: Handle this material following standard medical practices and following the recommendations presented on the Package Insert.

PROTECTIVE PRACTICES DURING MAINTENANCE OF CONTAMINATED EQUIPMENT: When cleaning non-disposable equipment, wear latex or butyl rubber gloves (double gloving is recommended), goggles, and lab coat. Wash equipment with soap and water. Wipe equipment down with damp sponge or polypad.

8. EXPOSURE CONTROLS - PERSONAL PROTECTION

VENTILATION AND ENGINEERING CONTROLS: Use with adequate ventilation. Follow standard medical product handling procedures. During decontamination of work surfaces, workers should wear the same equipment recommended in Section 6 (Accidental Release Measures) of this MSDS.

EXPOSURE LIMITS/GUIDELINES:

CHEMICAL NAME	CAS #	EXPOSURE LIMITS IN AIR									
		ACGIH-TLV		OSHA-PEL		NIOSH-RELS		AIHA WEELs		NIOSH IDLH	OTHER
		TWA	STEL	TWA	STEL	TWA	STEL	TWA	STEL		
Oxybutynin	5633-20-5	NE	NE	NE	NE	NE	NE	NE	NE	NE	10
Triacetin	102-76-1	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Duro-Tak® Acrylic Copolymer Adhesive	Mixture	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

NE = Not Established. See Section 16 for Definitions of Terms Used.

INTERNATIONAL OCCUPATIONAL EXPOSURE LIMITS: Currently there are no international exposure limits for the components of this product.

RESPIRATORY PROTECTION: A respirator is not required for routine conditions of use of this product.

EYE PROTECTION: Not normally needed during normal use.

HAND PROTECTION: For situations in which prolonged skin contact is anticipated, double glove, using latex, nitrile, or rubber gloves. Check gloves for leaks. Wash hands before putting on gloves and after removing gloves. Gloves should cover the gown cuff.

BODY PROTECTION: Use appropriate protective clothing for the task (e.g., lab coat, etc.)

9. PHYSICAL and CHEMICAL PROPERTIES

BOILING POINT: Not established.

FREEZING/MELTING POINT Not established.

EVAPORATION RATE (nBuAc = 1): Not established.

SOLUBILITY IN WATER: Not soluble.

VAPOR PRESSURE (air = 1): Not established.

SPECIFIC GRAVITY (water = 1): Not established

ODOR THRESHOLD: Not established.

pH: Not established.

COEFFICIENT WATER/OIL DISTRIBUTION: Not established.

APPEARANCE AND COLOR: This product is translucent patch with an adhesive on one side and is packaged in a foil-backed pouch.

HOW TO DETECT THIS SUBSTANCE (warning properties): The appearance of this product is a distinguishing characteristic.

10. STABILITY and REACTIVITY

STABILITY: This product is stable.

DECOMPOSITION PRODUCTS: If exposed to extremely high temperatures, the products of thermal decomposition may include irritating fumes and toxic gases (e.g., carbon oxides and nitrogen oxides).

MATERIALS WITH WHICH SUBSTANCE IS INCOMPATIBLE: This product is generally compatible with other common materials in a medical facility. Acids, caustics, and other chemicals that could affect its performance should be avoided.

HAZARDOUS POLYMERIZATION: Will not occur.

CONDITIONS TO AVOID: Avoid heat, light, and contact with incompatible chemicals.

11. TOXICOLOGICAL INFORMATION

GENERAL TOXICITY INFORMATION: Individuals who have had allergic reactions to products containing Oxybutynin or any of the other ingredients in this product may experience allergic reactions to this product. Symptoms described in patients given therapeutic doses of this substance include the following:

This product can cause blurred vision, constipation, decreased sweating, dizziness, drowsiness, dry mouth, pain or difficulty passing urine, sexual difficulties (impotence), confusion, nervousness, difficulty breathing, eye pain, fever, flushing (reddening of the skin), memory loss, palpitations, skin rash (hives), itching, central nervous system excitation, flushing, fever, dehydration, cardiac arrhythmia, vomiting, and urinary retention.

SYMPTOMS OF OVEREXPOSURE BY ROUTE OF EXPOSURE:

The health hazard information provided below is pertinent to medical employees using this product in an occupational setting. This product is designed for administration via a transdermal patch system. The following paragraphs describe the symptoms of exposure by route of exposure.

INHALATION: Due to the form of this product, inhalation is not a significant route of occupational overexposure. Inhalation of vapors of this product may slightly irritate the nose, throat, and lungs. Symptoms are generally alleviated upon breathing fresh air.

CONTACT WITH SKIN or EYES: Contact with the skin may cause mild irritation, which is alleviated upon rinsing. Symptoms of skin exposure may include itching and rash. Individuals who have had allergic reactions to products containing Oxybutynin or any of the other ingredients in this product may experience allergic reactions to this product. Contact of this product with the eyes can cause irritation, redness, and tearing.

SKIN ABSORPTION: This product is designed to be absorbed via intact skin. Systemic absorption of therapeutic doses of Oxybutynin may cause symptoms described in "Other Potential Health Effects".

INGESTION: Ingestion is not a significant route of occupational overexposure. Symptoms from ingestion of therapeutic doses caused by poor hygiene practices may include those described for "Other Potential Health Effects".

INJECTION: Though not anticipated to be a significant route of overexposure for this product, injection (via punctures or lacerations by contaminated objects) may cause redness at the site of injection. Symptoms may include those described for "Other Potential Health Effects".

OTHER POTENTIAL HEALTH EFFECTS-Therapeutic Doses: Employees administering the product should not experience adverse effects if handled properly. Adverse effects from therapeutic doses have included:

- Blurred vision, constipation, decreased sweating, dizziness, drowsiness, dry mouth, pain or difficulty passing urine, and sexual difficulties (impotence).
- Confusion, nervousness, difficulty breathing, eye pain, fever, flushing (reddening of the skin), memory loss, palpitations, skin rash (hives), and itching.
- Central nervous system excitation, flushing, fever, dehydration, cardiac arrhythmia, vomiting, and urinary retention.

HEALTH EFFECTS OR RISKS FROM EXPOSURE: An Explanation in Lay Terms. Overexposure to this product may cause the following health effects:

ACUTE: The primary health effects that may be experienced by medical personnel exposed to this product is mild irritation of contaminated skin. In the event of exposures to therapeutic doses of this product, effects described in "Other Potential Health Effects" may result.



HAZARDOUS MATERIAL IDENTIFICATION SYSTEM

HEALTH HAZARD	(BLUE)	2*
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FLAMMABILITY HAZARD	(RED)	1
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PHYSICAL HAZARD	(YELLOW)	0
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PROTECTIVE EQUIPMENT

EYES	RESPIRATORY	HANDS	BODY
	SEE SECTION 8		SEE SECTION 8

For Routine Industrial Use and Handling Applications

Hazard Scale: 0 = Minimal 1 = Slight 2 = Moderate
3 = Serious 4 = Severe * = Chronic hazard

11. TOXICOLOGICAL INFORMATION (Continued)

CHRONIC: Individuals who have had allergic reactions to products containing Oxybutynin or any of the other ingredients in this product may experience allergic reactions to this product. In the event of prolonged or repeated exposures to therapeutic doses of this product, effects described in "Other Potential Health Effects" may result. See Section 11 (Toxicological Information, for additional information).

TARGET ORGANS: ACUTE: Industrial Exposure: Skin. Therapeutic Doses: Skin. CHRONIC: Industrial Exposure: Skin. Therapeutic Doses: Eyes, gastrointestinal system, cardiovascular system, central nervous system, and skin.

IRRITANCY OF PRODUCT: This product can irritate contaminated tissue.

SENSITIZATION OF PRODUCT: Individuals who have had allergic reactions to products containing Oxybutynin or any of the other ingredients in this product may experience allergic reactions to this product.

TOXICITY DATA: The following are toxicity data for the active component of this product, Oxybutynin. This MSDS presents toxicity data currently available for the active component. Additional data are available for the active component and data are available for other components of this product, but are not presented in this MSDS. Contact Watson Pharmaceuticals for more information.

OXYBUTYNIN:

TDLo (intravenous, rat) = 10 mg/kg; Kidney, Ureter, Bladder: other changes

SUSPECTED CANCER AGENT: The components of this product are not found on the following lists: FEDERAL OSHA Z LIST, NTP, IARC, and CAL/OSHA and therefore are neither considered to be nor suspected to be cancer-causing agents by these agencies.

The free base form of Oxybutynin is pharmacologically equivalent to Oxybutynin Chloride. A 24-month study in rats at dosages of Oxybutynin Chloride of 20, 80, and 160 mg/kg showed no evidence of carcinogenicity. These doses are approximately 6, 25, and 50 times the maximum exposure in humans taking and oral dose based on body surface area

REPRODUCTIVE TOXICITY INFORMATION: Listed below is information concerning the effects of this product and its components on the human reproductive system.

Mutagenicity: Oxybutynin Chloride showed no increase of mutagenic activity when tested in *Schizosaccharomyces pompholiciformis*, *Saccharomyces cerevisiae*, and *Salmonella typhimurium* test systems.

Embryotoxicity: The components of this product are not reported to be embryotoxic in humans.

Teratogenicity: Subcutaneous administration to rats at doses up to 25 mg/kg (approximately 50 times the human exposure based on surface area) and to rabbits at doses up to 0.4 mg/kg (approximately 1 time the human exposure) revealed no evidence of harm to the fetus due to Oxybutynin Chloride.

Reproductive Toxicity: Reproduction studies with Oxybutynin Chloride in the mouse, rat, hamster, and rabbit showed no definite evidence of impaired fertility or harm to the animal fetus.

ACGIH BIOLOGICAL EXPOSURE INDICES (BEIs): Currently, ACGIH Biological Exposure Indices (BEIs) have not been determined for the components of this product.

12. ECOLOGICAL INFORMATION

ALL WORK PRACTICES MUST BE AIMED AT ELIMINATING ENVIRONMENTAL CONTAMINATION.

ENVIRONMENTAL STABILITY: The chemical (medicinal) components of this product will slowly degrade in the environment and form a variety of organic materials. The patch material may persist for a long period of time.

EFFECT OF MATERIAL ON PLANTS or ANIMALS: No specific information is currently available on the effect of this product on plants or animals in the environment. This product may be harmful to contaminated plant and animal life, especially in large quantities.

EFFECT OF CHEMICAL ON AQUATIC LIFE: No information is currently available on the effect of this product on aquatic plants or animals in the environment. Release of this product to an aquatic environment may be harmful to aquatic plant and animal life in contaminated bodies of water, especially in large quantities.

13. DISPOSAL CONSIDERATIONS

PREPARING WASTES FOR DISPOSAL: Waste disposal must be in accordance with appropriate U.S. Federal, State, and local regulations or with regulations of the EU and its member states or Canada and its Provinces. This product, if unaltered by handling, may be disposed of by treatment at a permitted facility or as advised by your local hazardous waste regulatory authority. All gowns, gloves, and disposable materials used in the preparation or handling of this drug should be disposed of in accordance with established hazardous waste disposal procedures. Handle as if capable of transmitting infectious agents. Incineration is recommended. Reusable equipment should be cleaned with soap and water.

U.S. EPA WASTE NUMBER: Not applicable to wastes consisting only of this product.

14. TRANSPORTATION INFORMATION

THIS PRODUCT IS NOT HAZARDOUS AS DEFINED BY 49 CFR 172.101 BY THE U.S. DEPARTMENT OF TRANSPORTATION.

PROPER SHIPPING NAME: Not Regulated
HAZARD CLASS NUMBER and DESCRIPTION: Not Applicable
UN IDENTIFICATION NUMBER: Not Applicable
PACKING GROUP: Not Applicable
DOT LABEL(S) REQUIRED: Not Applicable
EMERGENCY RESPONSE GUIDEBOOK NUMBER (2000): Not Applicable
MARINE POLLUTANT: No component of this product is classified by the U.S. DOT as a Marine Pollutant (as defined by 49 CFR 172.101, Appendix B).

TRANSPORT CANADA TRANSPORTATION OF DANGEROUS GOODS REGULATIONS: This product is not considered as Dangerous Goods, per regulations of Transport Canada.

INTERNATIONAL MARITIME ORGANIZATION (IMO) DESIGNATION: This product is not considered as Dangerous Goods by the International Maritime Organization.

EUROPEAN AGREEMENT CONCERNING THE INTERNATIONAL CARRIAGE OF DANGEROUS GOODS BY ROAD (ADR): This product is not considered by the United Nations Economic Commission for Europe to be dangerous goods.

15. REGULATORY INFORMATION

UNITED STATES REGULATIONS:

U.S. SARA REPORTING REQUIREMENTS: The components of this product are not subject to the reporting requirements of Sections 302, 304, and 313 of Title III of the Superfund Amendments and Reauthorization Act.

U.S. SARA THRESHOLD PLANNING QUANTITY: Not applicable.

U.S. CERCLA REPORTABLE QUANTITIES (RQ): Not applicable.

U.S. TSCA INVENTORY STATUS: This product is regulated under Food and Drug Administration standards; it is not subject to requirements under TSCA.

CALIFORNIA SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT (PROPOSITION 65): The components of this product are not on the California Proposition 65 lists.

OTHER U.S. FEDERAL REGULATIONS: Not applicable.

CANADIAN REGULATIONS:

CANADIAN DSL INVENTORY STATUS: This product regulated by the Therapeutic Products Programme (TPP) of Health Canada and so it is excepted from requirements of the DSL/NDSL Inventory.

CANADIAN ENVIRONMENTAL PROTECTION ACT (CEPA) PRIORITIES SUBSTANCES LISTS: The components of this product are not on the CEPA Priorities Substances Lists.

OTHER CANADIAN REGULATIONS: Not applicable.

CANADIAN WHMIS CLASSIFICATION AND SYMBOL: Class D2A/B (Materials Causing Other Toxic Effects)



16. OTHER INFORMATION

ANSI LABELING (Based on 129.1, Provided to Summarize Occupational Exposure Hazards): CAUTION! CAN CAUSE SKIN AND EYE IRRITATION. MAY CAUSE ALLERGIC REACTION. Avoid contact with skin, eyes, and clothing. Wash thoroughly after handling. Wear gloves, goggles, and appropriate body protection during handling or administration. **FIRST-AID:** In case of contact, flush skin or eyes with plenty of water. If adverse respiratory reaction occurs from allergic reaction, give oxygen and seek immediate medical attention. If ingested, DO NOT induce vomiting—seek immediate medical attention. **IN CASE OF FIRE:** Use water fog, dry chemical, CO₂, or “alcohol” foam. **IN CASE OF SPILL:** Pick up or sweep up spilled product. Place residual in appropriate container and seal. Dispose of according to applicable regulations. Consult Safety Data Sheet for additional information.

EU CLP REGULATION (EC) 1272/2008 LABELING AND CLASSIFICATION: According to Article 1, item 5 (a) of CLP Regulation (EC) 1272/2008, medicinal products in the finished state for human use, as defined in 2001/83/EC, are excepted from classification and other criteria of 1272/2008.

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16. OTHER INFORMATION (Continued)

COMPONENT GLOBAL HARMONIZATION, EU CLP REGULATION (EC) 1272/2008 LABELING AND CLASSIFICATION FULL TEXT:

Oxybutynin:

Classification: Acute Oral Toxicity Category 4; Target Organ Toxicity, repeated exposure, Category 2

Signal Word: Danger

Hazard Statements: H302; H373

Precautionary Statements: P280: Wear protective gloves/protective clothing/eye protection/face protection; P260: Do not breathe dust; P262: Do not get in eyes, on skin, or on clothing



Hazard Symbol/Pictograms:

ALL OTHER COMPONENTS:

These components do not meet the criteria for classification of hazardous.

COMPONENT EU 67/548/EEC LABELING AND CLASSIFICATION FULL TEXT:

Oxybutynin:

Hazard Classification: Harmful; Toxic

Risk Phrases: R22; R48



Hazard Symbol:

ALL OTHER COMPONENTS:

EU Classification: An official classification for these substances has not been published in Commission Directives.

REFERENCES AND DATA SOURCES: Contact the supplier for information.

METHODS OF EVALUATING INFORMATION FOR THE PURPOSE OF CLASSIFICATION: Bridging principles were used to classify this product.

REVISION DETAILS: Updated with GHS info and added internal exposure limit

This Safety Data Sheet is offered pursuant to OSHA's Hazard Communication Standard, 29 CFR, 1910.1200. Other government regulations must be reviewed for applicability to this product. To the best of Allergan knowledge, the information contained herein is reliable and accurate as of this date; however, accuracy, suitability or completeness are not guaranteed and no warranties of any type, either express or implied, are provided. The information contained herein relates only to this specific product. If this product is combined with other materials, all component properties must be considered. Data may be changed from time to time. Be sure to consult the latest edition.

PREPARED BY:

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619/670-0609

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