# 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

**PRODUCT IDENTIFIER/TRADE/MATERIAL NAME**: **ENABLEX® (Darifenacin) TABLET, EXTENDED RELEASE**

Containing 7.5 or 15 mg Darifenacin Hydrobromide

**DESCRIPTION:** Darifenacin Hydrobromide Tablets

**PRODUCT USE:** Human Pharmaceutical

**USES ADVISED AGAINST:** Non-Pharmaceutical Use

**CHEMICAL NAME:** For Active Ingredient: (S)-2-{1-[2-(2,3-dihydrobenzofuran-5-yl)ethyl]-3-pyrrolidinyl}-2,2-diphenylacetamide hydrobromide

**CHEMICAL FAMILY:** For Active Ingredient: Diphenylmethane

**HOW SUPPLIED:** 7.5 and 15 mg Darifenacin Hydrobromide

**OTHER DESIGNATIONS:** 7.5 mg Round White Tablets: NDC:0430-0170-15; NDC:0430-0170-23; NDC:0430-0170-96; 15 mg Round Peach Tablet: NDC:0430-0171-15; NDC:0430-0171-23; NDC:0430-0171-96

**FORMULA:** For Active Ingredient: Darifenacin Hydrobromide: $C_{28}H_{30}N_2O_2$•HBr

**SUPPLIER OF THE SAFETY DATA SHEET**

| | |
|---|---|
| **RESPONSIBLE PARTY U.S.:** | **ALLERGAN** |
| **U.S. ADDRESS:** | 400 Interpace Parkway, Morris Corporate Center III<br>Parsippany, NJ 07054, USA |
| **U.S. BUSINESS PHONE/GENERAL SDS INFORMATION** | +1-800-272-5525 |
| **RESPONSIBLE PARTY EUROPE:** | |
| **EUROPEAN ADDRESS:** | |
| **EUROPEAN BUSINESS PHONE:** | |
| **EMERGENCY PHONE (U.S./NORTH AMERICA):** | CHEMTREC: 1-800-424-9300 (24 hours) U.S., Canada, Puerto Rico |
| **EMERGENCY PHONE (OUTSIDE U.S.):** | CHEMTREC: +1-703-527-3887 (24 hours) Outside North America |
| **Email:** | SDS@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:** November 26, 2015 **DATE OF REVISION:** New

## 2. HAZARDS 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 excepted from classification and other criteria of 1272/2008.

**EU 67/548/EEC LABELING AND CLASSIFICATION:** 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.

**EMERGENCY OVERVIEW:**

**Product Description:** This product is supplied as round tablets which are white or red.

**Health Hazards:** In the workplace, exposure via inhalation or eye contact may cause irritation. No information is available on possible effects from skin exposure. Accidental ingestion may be harmful. In therapeutic use, the most common adverse effects reported include constipation, dry mouth, headache, heartburn, nausea, urinary tract infection, blurred vision, heat exhaustion or heat-stroke. Somnolence has also been reported. May cause harm to the fetus during pregnancy, based on animal information. Other adverse effects seen from therapeutic use are described in Section 11 (Toxicological information).

**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 iron, titanium, carbon, magnesium, and nitrogen oxides and hydrogen bromide).

**Reactivity Hazards:** This product is not reactive.

**Environmental Hazards:** The active ingredient can cause long-term harm to algae and other aquatic organisms. Large quantities of this product released to the aquatic and terrestrial environment may have an adverse effect.

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

## 3. COMPOSITION and INFORMATION ON INGREDIENTS

| CHEMICAL NAME | CAS # | EINECS # | % w/w | LABEL ELEMENTS<br>EU Classification (67/548/EEC)<br>GHS & EU Classification (1272/2008 EC)<br>Risk Phrases/Hazard Statements/Symbol |
|---|---|---|---|---|
| ACTIVE INGREDIENTS: | | | | |
| Darifenacin Hydrobromide<br>(S)-2-{1-[2-(2,3-dihydrobenzofuran-5-yl)ethyl]-3-pyrrolidinyl}-2,2-diphenylacetamide hydrobromide | 133099-07-7 | Not Listed | Proprietary | SELF-CLASSIFICATION<br>EU 67/548<br>Classification: Reproductive Toxicity Cat. 3, Irritant, Dangerous for the Environment<br>Risk Phrase Codes: R63, R36, R52/53<br>Hazard Symbols: Xn/Xi<br>GHS and EU 1272/2008<br>Classification: Reproductive Toxicity Cat. 2, Eye Irritation Cat. 2A, Aquatic Chronic Toxicity Cat. 2<br>Hazard Codes: H361d, H319, H412<br>Hazard Symbol/Pictogram: GHS07, GHS08 |
| EXCIPIENTS: | | | | |
| Dibasic Calcium Phosphate Anhydrous | 7789-77-7 | For Dibasic: 231-826-1 | Proprietary | EU (67/548/EEC): No Classification Applicable<br>EU/GHS 1272/2008: No Classification Applicable |
| Ferric Oxide Red (15 mg only) | 1309-37-1 | 215-168-2 | Proprietary | EU (67/548/EEC): No Classification Applicable<br>EU/GHS 1272/2008: No Classification Applicable |
| Ferric Oxide Yellow (15 mg only) | 20344-49-4 | 243-746-4 | Proprietary | EU (67/548/EEC): No Classification Applicable<br>EU/GHS 1272/2008: No Classification Applicable |
| Hypromellose | 9004-65-3 | Not Listed | Proprietary | EU (67/548/EEC): No Classification Applicable<br>EU/GHS 1272/2008: No Classification Applicable |
| Magnesium Stearate | 557-04-0 | 209-150-3 | Proprietary | EU (67/548/EEC): No Classification Applicable<br>EU/GHS 1272/2008: No Classification Applicable |
| Talc | 14807-96-6 | 238-877-9 | Proprietary | EU (67/548/EEC): No Classification Applicable<br>EU/GHS 1272/2008: No Classification Applicable |
| Titanium Dioxide | 13463-67-7 | 236-675-5 | Proprietary | EU (67/548/EEC): No Classification Applicable<br>EU/GHS 1272/2008: No Classification Applicable |

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

## 4 FIRST-AID MEASURES

**PROTECTION OF FIRST AID RESPONDERS:** First-aid responders should not attempt to treat victims of exposure to this material without adequate personal protective equipment. Rescuers should be taken for medical attention, if necessary.

**DESCRIPTION OF FIRST AID MEASURES:** Victim(s) must be taken for medical attention. Remove victim(s) to fresh air, as quickly as possible. Only trained personnel should administer supplemental oxygen and/or cardio-pulmonary resuscitation, when necessary. Take copy of label and SDS to physician or other health professional with victim(s).

**Inhalation:** If dusts or particulates from this product are inhaled, remove victim to fresh air. If necessary, use artificial respiration to support vital functions. Seek medical attention if adverse effect occurs after removal to fresh air.

**Skin Exposure:** If the product contaminates the skin and adverse effect occurs, begin decontamination with running water. Minimum flushing is for 20 minutes. Do not interrupt flushing. Remove exposed or contaminated clothing, taking care not to contaminate eyes. Seek medical attention if adverse effect occurs after flushing.

**Eye Exposure:** If particulates from this product enter the eyes, open victim's eyes while under gently running water. Use sufficient force to open eyelids. Have victim "roll" eyes. Minimum flushing is for 20 minutes. Do not interrupt flushing. Seek immediate medical attention after flushing if adverse effect occurs.

**Ingestion Exposure:** 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. Rinse mouth with water immediately. Victim should drink large quantities of water. If milk is available, victim should drink it after drinking water. Never induce vomiting or give diluents (milk or water) to someone who is unconscious, having convulsions, or unable to swallow.

**IMPORTANT SYMPTOMS AND EFFECTS:** See Sections 2 (Hazard Identification) and 11 (Toxicological Information).

**MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE:** In therapeutic use, pre-existing uncontrolled narrow-angle glaucoma, disorders causing urinary retention, gastric retention may be aggravated. Workplace exposure may also aggravate these conditions. Persons who may have hypersensitivity reactions to any ingredient or other disorders described in Section 11 (Toxicological Information) may experience aggravation upon exposure.

**IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT NEEDED:** Treat symptoms and eliminate exposure. Persons developing hypersensitivity reactions should receive immediate medical attention. No specific antidote is known. Treatment should be symptomatic and supportive. In the event of overdosage, ECG monitoring is recommended. Enablex has been administered in clinical trials at doses up to 75 mg (five times the maximum therapeutic dose) and signs of overdose were limited to abnormal vision.

## 5. FIRE-FIGHTING MEASURES

**FLASH POINT:** Not established.

**AUTOIGNITION TEMPERATURE:** Not established.

**FLAMMABLE LIMITS & METHOD OF DETERMINATION (in air by volume, %):** Not determined.

**FIRE EXTINGUISHING MEDIA:** Use extinguishing media appropriate for surrounding fire.

**UNSUITABLE EXTINGUISHING MEDIA:** None known.

## 5. FIRE-FIGHTING MEASURES

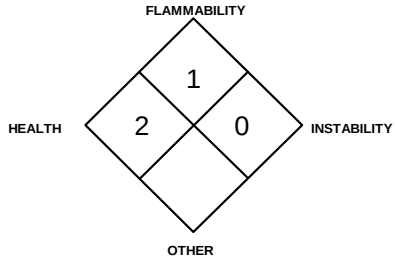
**SPECIFIC HAZARDS ARISING FROM THE CHEMICAL:** This product may ignite if highly heated for a prolonged period of time. When involved in a fire, the products of thermal decomposition may include irritating fumes and toxic gases (e.g., carbon, iron, titanium, magnesium, and nitrogen oxides and hydrogen bromide).

Explosion Sensitivity to Mechanical Impact: Not sensitive.

Explosion Sensitivity to Static Discharge: Not sensitive.

**SPECIAL PROTECTIVE ACTIONS FOR FIRE-FIGHTERS:** Incipient fire responders should wear eye protection. Structural firefighters must wear Self-Contained Breathing Apparatus (SCBA) and full protective equipment. Contaminated protective equipment 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.

**NFPA RATING**




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

## 6. ACCIDENTAL RELEASE MEASURES

**PERSONAL PRECAUTIONS:** In the event of a spill, clear the area and protect people.

**PROTECTIVE EQUIPMENT:**

Small Spills: For incidental spills (e.g., 1 vial of tablets), wear double latex or nitrile disposable gloves and eye protection.

Large Spills: For large spills (e.g., a pallet of vials), protective apparel should be used with a respirator when there is any danger of airborne dusts being generated. Minimum Personal Protective Equipment should be rubber gloves, rubber boots, face shield, and Tyvek suit.

**METHODS FOR CLEANUP AND CONTAINMENT:**

Small Spills: Pick-up or sweep-up spilled tablets.

Large Spills: Trained personnel following pre-planned procedures should handle non-incidental releases. Access to the spill areas should be restricted. Sweep up spilled product carefully, avoiding the generation of airborne dusts.

All Spills: Decontaminate the area of the spill thoroughly using detergent and water. Place all spill residue in an appropriate container and seal. Move to a secure area. Do not mix with wastes from other materials. If necessary, discard contaminated response equipment or rinse with soapy water before returning such equipment to service. Dispose of in accordance with applicable international, national, state, and local procedures (see Section 13, Disposal Considerations).

**ENVIRONMENTAL PRECAUTIONS:** Prevent material from entering sewer or confined spaces, waterways, soil or public waters. Do not flush to sewer. For spills on water, contain, minimize dispersion and collect.

## 7. HANDLING and USE

**PRECAUTIONS FOR SAFE HANDLING:** Employees must be trained to properly use this compound. Particular care in working with this material must be practiced in pharmacies and other preparation areas, during manufacture of pharmaceutical preparations, and during patient administration. Use of this compound should be performed in a designated area for working with narcotic compounds. As with all chemicals, avoid getting this product ON YOU or IN YOU. Do not eat, drink, smoke, or apply cosmetics in work areas where this product is handled or stored. Wash thoroughly after handling this product or equipment and containers of this product. Follow SPECIFIC USE INSTRUCTIONS supplied with this product. Use of this product should be performed in a designated area for working with drugs. Particular care in working with this product must be practiced in pharmacies and other preparation areas, during manufacture of this product, and during patient administration. If necessary, work areas must be regularly cleaned and decontaminated.

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

**CONDITIONS FOR SAFE STORAGE:** Containers of this product must be properly labeled. Store this product in original container. Store at 20°C to 25°C (68°F to 77°F). (See USP Controlled Room Temperature.) Inspect bottles containing this product for leaks or damage. Store away from incompatible materials (see Section 10, Stability and Reactivity).

**SPECIFIC END USE(S):** This product human pharmaceutical. Follow all industry standards for use of this product.

## 8. EXPOSURE CONTROLS - PERSONAL PROTECTION

**EXPOSURE LIMITS/CONTROL PARAMETERS:**

**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 SDS.

**Occupational/Workplace Exposure Limits/Guidelines:**

| CHEMICAL NAME | CAS # | EXPOSURE LIMITS IN AIR | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | ACGIH-TLVs | | OSHA-PELs | | NIOSH-RELs | | NIOSH | OTHER |
| | | TWA $mg/m^3$ | STEL $mg/m^3$ | TWA $mg/m^3$ | STEL $mg/m^3$ | TWA $mg/m^3$ | STEL $mg/m^3$ | IDLH $mg/m^3$ | $mg/m^3$ |
| Darifenacin Hydrobromide | 133099-07-7 | NE | NE | NE | NE | NE | NE | NE | Watson OEL: 40 $\mu g/m^3$ |

NE = Not Established.

## 8. EXPOSURE CONTROLS - PERSONAL PROTECTION (Continued)

### EXPOSURE LIMITS/CONTROL PARAMETERS (continued):

**Occupational/Workplace Exposure Limits/Guidelines (continued):**

| CHEMICAL NAME | CAS # | EXPOSURE LIMITS IN AIR | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | ACGIH-TLVs | | OSHA-PELs | | NIOSH-RELs | | NIOSH | OTHER |
| | | TWA mg/m$^3$ | STEL mg/m$^3$ | TWA mg/m$^3$ | STEL mg/m$^3$ | TWA mg/m$^3$ | STEL mg/m$^3$ | IDLH mg/m$^3$ | mg/m$^3$ |
| Dibasic Calcium Phosphate Anhydrous | 7789-77-7 | NE | NE | NE | NE | NE | NE | NE | NE |
| Ferric Oxide Red<br>Ferric Oxide Yellow<br>Exposure limits given are for CAS# 1309-37-1 (Fe2O3) | 1332-37-2<br>20344-49-4 | 5 (resp. fract.) | NE | 10 (fume) | NE | 5 (dusts & fume, as Fe) | NE | 2500 (dust & fume, as Fe) | Carcinogen: IARC-3, MAK-3B, TLV-A4 |
| Hypromellose<br>Exposure limits are for cellulose | 9004-65-3 | 10 | NE | 15 (total dust), 5 (respirable fraction) | NE | 10 (total dust), 5 (respirable fraction) | NE | NE | Carcinogen: IARC-3 |
| Magnesium Stearate | 557-04-0 | 10 | NE | NE | NE | NE | NE | NE | Carcinogen: TLV-A4 |
| Polyethylene Glycol | 25322-68-3 | NE | NE | NE | NE | NE | NE | NE | DFG MAKs:<br>TWA = 1000 (inhalable fraction); due to possible mist formation, exposure should be minimized.<br>PEAK = 8•MAK 15 min. average value, 1-hr interval, 4 per shift<br>DFG MAK Pregnancy Risk Classification: C<br>AIHA WEEL<br>TWA = 10 |
| Talc | 14807-96-6 | 2 (resp. fract.) | NE | 20 mppcf (containing < 1% quartz) | NE | 2 (respirable dust) and < 1% quartz | NE | NE | Carcinogen: IARC-3, MAK-3B (respirable fraction), TLV-A4 |
| Titanium Dioxide | 13463-67-7 | 10 | NE | 15 (total dust)<br>10 (vacated 1989 PEL) | NE | See NIOSH Pocket Guide Appendix A | | Ca, 5000 | Carcinogen: IARC-2B, MAK-3A, NIOSH-Ca, TLV-A4; NIC: TLV-A3 |

NE = Not Established. NIC = Notice of Intended Change

**International Occupational Exposure Limits:** In addition to the exposure limit values cited in this section, other exposure limits have been established by various countries for the components of this product. The exposure limits given may not be the most current; individual country authorities should be contacted to check on more current limits.

**HYPROMELLOSE:**
Russia: STEL = 10 mg/m$^3$, JUN 2003

**IRON OXIDES:**
ARAB Republic of Egypt: TWA = 3 ppm (5 mg/m$^3$) (fume), JAN 1993
Australia: TWA = 0.1 mg(Fe)/m$^3$, JUL 2008
Australia: TWA = 5 mg(Fe)/m$^3$ (fume), JUL 2008
Belgium: TWA = 2 ppm (5 mg(Fe)/m$^3$) (fume), MAR 2002
Denmark: TWA = 3.5 mg(Fe)/m$^3$, OCT 2002
Finland: TWA = 5 mg(Fe)/m$^3$, fume, SEP 2009
France: VME = 5 mg(Fe)/m$^3$ (fume), FEB 2006
Germany: MAK = 1.5 mg(Fe)/m$^3$ (respirable), 2005
Hungary: TWA = 6 mg/m$^3$ (resp), SEP 2000
Japan: OEL = 1 mg/m$^3$ (respirable), 4 mg/m$^3$ (total), APR 2007
Korea: TWA = 10 mg/m$^3$, 2006
Korea: TWA = 5 mg/m$^3$, 2006
Mexico: TWA = 10 mg/m$^3$; STEL = 20 mg/m$^3$, 2004
The Netherlands: MAC-TGG = 5 mg(Fe)/m$^3$, 2003
The Netherlands: MAC-TGG = 10 mg/m$^3$, 2003
New Zealand: TWA = 5 mg(Fe)/m$^3$ (dust and fume), JAN 2002
New Zealand: TWA = 10 mg/m$^3$ (inspirable dust), JAN 2002
Norway: TWA = 3 mg/m$^3$, JAN 1999
The Philippines: TWA = 10 mg/m$^3$ (fume), JAN 1993
Poland: MAC(TWA) fume = 5 mg/m$^3$, MAC(STEL) = 10 mg/m$^3$, JAN 1999
Russia: TWA = 6 mg/m$^3$, JUN 2003
Sweden: TWA = 3.5 mg(Fe)/m$^3$ (resp. dust), JUN 2005
Switzerland: MAK-W = 3 mg/m$^3$, DEC 2006

**IRON OXIDES (continued):**
Thailand: TWA = 10 mg/m$^3$ (fume), JAN1993
Turkey: TWA = 10 mg/m$^3$ (fume), JAN 1993
United Kingdom: TWA = 4 mg/m$^3$ (respirable), 2005
United Kingdom: TWA = 10 mg/m$^3$ (inhalable), 2005
United Kingdom: TWA = 5 mg(Fe)/m$^3$;STEL = 10 mg(Fe)/m$^3$, 2005
In Argentina, Bulgaria, Colombia, Jordan, Singapore, Vietnam check ACGIH TLV

**MAGNESIUM STEARATE:**
New Zealand: TWA = 10 mg/m$^3$ (inspirable dust), JAN 2002
Sweden: TWA = 5 mg/m$^3$, JUN 2005
Belgium: TWA = 10 mg/m$^3$, MAR 2002

**POLYETHYLENE GLYCOL:**
The Netherlands: MAC-TGG = 1000 mg/m$^3$, 2003
Russia: STEL = 10 mg/m$^3$, JUN 2003
Denmark: TWA = 1000 mg/m$^3$, OCT 2002
Germany: MAK = 1000 mg/m$^3$ (inhalable), 2005

**TALC:**
Australia: TWA = 2.5 mg/m$^3$, JUL 2008
Austria: MAK-TMW = 2 mg/m$^3$, resp, 2007
Belgium: TWA = 2 mg/m$^3$, MAR 2002
Denmark: TWA = 0.3 f/cc, carc, MAY 2011
Finland: TWA = 0.5 mg/m$^3$, NOV 2011
Finland: TWA = 5 mg/m$^3$, granulated, SEP 2009
Iceland: TWA = 0.3 f/cc, NOV 2011
Japan: OEL = 0.5 mg/m$^3$ (resp. dust), 2 mg/m$^3$ (total dust), MAY 2009
Korea: TWA = 2 mg/m$^3$, 2006
Mexico: TWA = 2 mg/m$^3$ (respirable), 2004
The Netherlands: MAC-TGG = 1 mg/m$^3$, 2003
New Zealand: TWA = 2 mg/m$^3$ (respirable dust), JAN 2002

**TALC (continued):**
Peru: TWA = 2 mg/m$^3$, JUL 2005
Sweden: TWA = 2 mg/cm$^3$ (total dust); TWA = 1 mg/cm$^3$ (resp. dust), JUN 2005
Switzerland: MAK-W = 2 mg/m$^3$, DEC 2006
United Kingdom: TWA = 1 mg/m$^3$ (resp. dust), OCT 2007
In Argentina, Bulgaria, Colombia, Jordan, Singapore, Vietnam check ACGIH TLV

**TITANIUM DIOXIDE:**
ARAB Republic of Egypt: TWA = 15 mg/m$^3$, JAN 1993
Belgium: TWA = 10 mg/m$^3$, MAR 2002
Denmark: TWA = 6 mg(Ti)/m$^3$, OCT 2002
France: VME = 10 mg/m$^3$, FEB 2006
Germany: MAK = 1.5 mg/m$^3$ (respirable), 2005
Japan: OEL = 1 mg/m$^3$ (respirable), 4 mg/m$^3$ (total), APR 2007
Korea: TWA = 10 mg/m$^3$, 2006
Mexico: TWA = 10 mg(Ti)/m$^3$; STEL = 20 mg(Ti)/m$^3$, 2004
The Netherlands: MAC-TGG = 10 mg/m$^3$, 2003
New Zealand: TWA = 10 mg/m$^3$ (inspirable dust), JAN 2002
Norway: TWA = 5 mg/m$^3$, JAN 1999
Poland: MAC(TWA) = 10 mg(Ti)/m$^3$, MAC(STEL) = 30 mg(Ti)/m$^3$, JAN 1999
Russia: TWA = 10 mg/m$^3$, JUN 2003
Sweden: TWA = 5 mg/m$^3$ (total dust), JUN 2005
Switzerland: MAK-W = 3 mg/m$^3$, DEC 2006
Turkey: TWA = 15 mg/m$^3$, JAN 1993
United Kingdom: TWA = 10 mg/m$^3$ (inhalable), 2005
United Kingdom: TWA = TWA 4 mg/m$^3$ (respirable), 2005
In Argentina, Bulgaria, Colombia, Jordan, Singapore, Vietnam check ACGIH TLV

**PERSONAL PROTECTIVE EQUIPMENT:** Use of personal protective equipment must be in compliance with U.S. OSHA 29 CFR Subpart I (beginning at 1910.132), Canadian CSA Standards Z94.4-02 and Z94.3-02, EU EN 529:2005, CEN/TR 15419:2006, and CR 13464:1999. Please reference applicable regulations and standards for relevant details.

**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.

## 8. EXPOSURE CONTROLS - PERSONAL PROTECTION (Continued)

**PERSONAL PROTECTIVE EQUIPMENT (continued):**

**Eye Protection:** No eye protection is normally needed during medical administration of this product. During operations in which dusts of the product may be generated, splash goggles or safety glasses should be considered.

**Hand Protection:** During medical administration of this product, medical latex or nitrile gloves should be worn to avoid absorption of the product. During manufacture or other similar industrial operations, wear the appropriate hand protection for the process. Use double gloves for spill response, as stated in Section 6 (Accidental Release Measures) of this SDS.

**Body Protection:** Use appropriate protective clothing for the task (e.g., lab coat, etc.)

## 9. PHYSICAL and CHEMICAL PROPERTIES

The following information is for the product.

**FORM:** Round tablets.
**COLOR:** White or red.
**ODOR:** Odorless.
**ODOR THRESHOLD:** Not applicable.

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

The following values are available for the active ingredient, Darifenacin Hydrobromide:

**FORM:** Crystalline solid.
**COLOR:** White to off-white.
**MOLECULAR FORMULA:** $C_{28}H_{30}N_2O_2$•HBr
**MOLECULAR WEIGHT:** 507.5
**ODOR:** Slight.
**ODOR THRESHOLD:** Not available.
**BOILING POINT @ 760 mmHg:** 614.3°C (1137.7°F) [predict.]
**MELTING POINT:** 228-230°C (442.4-446°F)
**VAPOR PRESSURE (air = 1) @ 25°C:** Not available.
**SPECIFIC GRAVITY (water = 1):** Not available.
**EVAPORATION RATE (nBuAc = 1):** Not applicable.
**pH:** Not available.
**FLASH POINT:** Not available.
**DECOMPOSITION TEMPERATURE:** Not available.
**SOLUBILITY IN WATER @ 25°C:** Soluble in water.
**COEFFICIENT WATER/OIL DISTRIBUTION:** Log P: 4.5

**OTHER SOLUBILITIES:** Soluble in chloroform, dimethylsulfoxide, methanol, and ethanol.

## 10. STABILITY and REACTIVITY

**CHEMICAL STABILITY:** This product is not reactive.

**DECOMPOSITION PRODUCTS:** *Combustion:* If exposed to extremely high temperatures, the products of thermal decomposition may include irritating fumes and toxic gases (e.g. carbon, iron, magnesium, titanium, and nitrogen oxides and hydrogen bromide). *Hydrolysis:* None known.

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

**POSSIBILITY HAZARDOUS REACTION/POLYMERIZATION:** Will not occur.

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

## 11. TOXICOLOGICAL INFORMATION

**SYMPTOMS OF EXPOSURE BY ROUTE OF EXPOSURE:** The health hazard information provided below is pertinent to medical employees using this product in an occupational setting. The following paragraphs describe the symptoms of exposure by route of exposure.

**Inhalation:** Inhalation of airborne dusts generated from the drug product may slightly irritate the nose, throat, and lungs. Inhalation of large amounts may also cause under 'Other Potential Health Effects'.

**Contact with Skin or Eyes:** Acute skin contact is not expected to cause adverse effect. Prolonged or repeated skin contact may cause dermatitis (dry, red skin). Contact with the eyes of airborne dusts generated by damaged tablets of this product may cause mild to moderate irritation, redness, and tearing.

**Skin Absorption:** No information available.

**Ingestion:** Ingestion is not a significant route of occupational overexposure. Acute ingestion of large quantities of this product caused by poor hygiene practices may be harmful. Symptoms of prolonged or repeated ingestion, as may occur when poor industrial hygiene is practiced, may include those described for 'Other Potential Health Effects'.

**Injection:** Injection is not a likely route of exposure for the form of this product.

**OTHER POTENTIAL HEALTH EFFECTS-Therapeutic Doses:** In therapeutic use, the most common adverse effects reported include constipation, dry mouth, headache, heartburn, nausea, urinary tract infection, blurred vision, heat exhaustion or heat-stroke. Somnolence has also been reported. May cause harm to the fetus during pregnancy, based on animal information.

**HAZARDOUS MATERIAL IDENTIFICATION SYSTEM**

| | | |
|---|---|---|
| **HEALTH HAZARD** | (BLUE) | 2* |
| **FLAMMABILITY HAZARD** | (RED) | 1 |
| **PHYSICAL HAZARD** | (YELLOW) | 0 |

**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

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

Acute: Accidental ingestion may be harmful. Eye contact with dusts may cause mechanical irritation. Inhalation of dusts from product may also cause effects described under 'Other Potential Health Effects'.

Chronic: Repeated workplace exposure to the skin contact may cause dermatitis (dry, red skin). Chronic therapeutic use or workplace exposure may cause effects described under 'Other Potential Health Effects'.

**TARGET ORGANS:** Acute: *Industrial Exposure*: Skin, eyes, respiratory system (dusts from product). *Therapeutic Doses*: Reproductive system. Chronic: *Industrial Exposure*: Skin. *Therapeutic Doses*: Body systems as given under 'Other Potential Health Effects'.

**IRRITANCY OF PRODUCT:** Dusts from this product may irritate contaminated tissue.

**SENSITIZATION TO THE PRODUCT:** No specific information available.

**TOXICITY DATA:** Currently the following toxicity data are available for the active component. Data for excipients are also available but are not presented in this SDS. Contact Allergan for more information.

**DARIFENACIN HYDROBROMIDE:**
$LD_{50}$ (Rat-Skin) > 2000 mg/kg
LD (Oral-Rat) 100-200 mg/kg

**CARCINOGENIC POTENTIAL OF COMPONENTS:** Carcinogenicity studies with Darifenacin were conducted in mice and rats. No evidence of drug-related carcinogenicity was revealed in a 24-month study in mice at dietary doses up to 100 mg/kg/day or approximately 32 times the estimated free plasma AUC reached at the maximum recommended human dose (the AUC at the MRHD) of 15 mg and in a 24-month study in rats at doses up to 15 mg/kg/day or up to approximately 12 times the AUC at the MRHD in female rats and approximately eight times the AUC at the MRHD in male rats. This material is not listed by agencies tracking the carcinogenic potential of chemical compounds.

The following excipient ingredients are listed:

**IRON OXIDES (based on CAS# 1309-37-1):** ACGIH TLV-A4 (Not Classifiable as a Human Carcinogen); IARC-3 (Unclassifiable as to Carcinogenicity in Humans); MAK-3B [respirable fraction] (Substances for Which in vitro tests or animal studies have yielded evidence of carcinogenic effects that is not sufficient for classification of the substance in one of the other categories.)

**MAGNESIUM STEARATE (as a stearate compound):** ACGIH TLV-A4 (Not Classifiable as Human Carcinogen)

**TALC:** ACGIH TLV-A4 (Not Classifiable as a Human Carcinogen); IARC-3 (Unclassifiable as to Carcinogenicity in Humans); MAK-3B [respirable fraction]: (Substances Which Cause Concern that They Could Be Carcinogenic for Man but Cannot Be Assessed Conclusively Because of Lack of Data. Substances for which in vitro tests or animal studies have yielded evidence of carcinogenic effects that is not sufficient for classification of the substance in one of the other categories.)

The remaining components of this product are not found on the following lists: U.S. EPA, U.S. NTP, U.S. OSHA, U.S. NIOSH, GERMAN MAK, IARC, or ACGIH and therefore are neither considered to be nor suspected to be cancer-causing agents by these agencies.

**REPRODUCTIVE TOXICITY INFORMATION:** There are no adequate and well-controlled studies of this product or Darifenacin Hydrobromide in pregnant women; this product may cause fetal harm when administered to a pregnant woman. In the workplace, the risk to the fetus should be communicated and the appropriate action should be taken to prevent exposure in accordance with company policy and regulatory requirements. This product is rated by the FDA for therapeutic risk as Pregnancy Risk Category C (Animal reproduction studies have shown an adverse effect on the fetus and there are no adequate and well-controlled studies in humans, but potential benefits may warrant use of the drug in pregnant women despite potential risks).

**Mutagenicity:** Darifenacin was not genotoxic in the bacterial mutation assay (Ames test), the Chinese hamster ovary assay, the human lymphocyte assay, or the in vivo mouse bone marrow cytogenetics assay.

**Embryotoxicity/Teratogenicity:** Darifenacin was not teratogenic in rats and rabbits at plasma exposures of free drug (via AUC) up to 59 times and 28 times, respectively (doses up to 50 and 30 mg/kg/day, respectively) the maximum recommended human dose [MRHD] of 15 mg. At approximately 59 times the MRHD in rats, there was a delay in the ossification of the sacral and caudal vertebrae which was not observed at approximately 13 times the AUC. Dystocia was observed in dams at approximately 17 times the AUC (10 mg/kg/day). Slight developmental delays were observed in pups at this dose. At five times the AUC (3 mg/kg/day), there were no effects on dams or pups. In rabbits, an exposure approximately 28 times (30 mg/kg/day) the MRHD of Darifenacin was shown to increase post-implantation loss, with a no effect level at nine times (10 mg/kg/day) the AUC at the MRHD. Dilated ureter and/or kidney pelvis was also observed in offspring at this dose along with urinary bladder dilation consistent with the pharmacological action of Darifenacin, with one case observed at nine times (10 mg/kg/day). No effect was observed at approximately 2.8 times (3 mg/kg/day) the AUC at the MRHD.

**Reproductive Toxicity:** There was no evidence for effects on fertility in male or female rats treated at oral doses up to approximately 78 times (50 mg/kg/day) the AUC at the MRHD. Darifenacin is excreted into the milk of rats. It is not known whether Darifenacin is excreted into human milk. Because many drugs are excreted in human milk, and because of the potential for serious adverse reactions in nursing infants, nursing mothers should be advised of these effects and the appropriate action should be taken to prevent exposure.

**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.

**MOBILITY:** This product has not been tested for mobility in soil.

**PERSISTENCE AND BIODEGRADABILITY:** This product has not been tested for persistence or biodegradability. It is expected that the components will slowly degrade in the environment and form a variety of organic and inorganic materials; however, no specific information is known.

## 12. ECOLOGICAL INFORMATION (Continued)

**BIO-ACCUMULATION POTENTIAL:** This product has not been tested for bio-accumulation potential.

**ECOTOXICITY:** This product may be harmful to aquatic and terrestrial organisms; all releases to terrestrial, atmospheric and aquatic environments should be avoided. The active ingredient can cause long-term harm to algae and other aquatic organisms.

**DARIFENACIN HYDROBROMIDE:**

$IC_{50}$ (*Skeletonema* Algae) 96 hours = 0.7 mg/L

$LC_{50}$ (*Daphnia magna*) 48 hours = 2.3 mg/L

**DARIFENACIN HYDROBROMIDE (continued):**

$LC_{50}$ (Mysid Shrimp) 48 hours = 2.1 mg/L

$LC_{50}$ (Oyster embryo) 48 hours = 0.44 mg/L

**OTHER ADVERSE EFFECTS:** This product does not contain any component with known ozone depletion potential.

**RESULTS OF PBT AND vPvB ASSESSMENT:** No Data Available. PBT and vPvB assessments are part of the chemical safety report required for some substances in European Union Regulation (EC) 1907/2006, Article 14.

**ENVIRONMENTAL EXPOSURE CONTROLS:** Controls should be engineered to prevent release to the environment, including procedures to prevent spills, atmospheric release and release to waterways.

## 13. DISPOSAL CONSIDERATIONS

**WASTE TREATMENT/DISPOSAL METHODS:** Waste disposal must be in accordance with appropriate Federal, State, and local regulations.

**PRECAUTIONS TO BE FOLLOWED DURING WASTE HANDLING:** Wear proper protective equipment when handling waste materials.

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

**EUROPEAN WASTE CODES:** Wastes from Human or Animal Health Care or Related Research: 18 01 08: Medicines Other Than Those Mentioned in 18 01 07.

## 14. TRANSPORTATION INFORMATION

**U.S. DEPARTMENT OF TRANSPORTATION REGULATIONS:** This product is not classified as dangerous goods, per U.S. DOT regulations, under 49 CFR 172.101.

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

**INTERNATIONAL AIR TRANSPORT ASSOCIATION (IATA):** This product is not classified as Dangerous Goods, by rules of IATA.

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

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

**TRANSPORT IN BULK ACCORDING TO THE IBC CODE:** Not applicable.

**ENVIRONMENTAL HAZARDS:** This product does not meet the criteria of environmentally hazardous according to the criteria of the UN Model Regulations (as reflected in the IMDG Code, ADR, RID, and ADN) and not component is specifically listed in Annex III under MARPOL 73/78.

## 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 (TPQ):** There are no specific Threshold Planning Quantities for any component of this product. The default Federal SDS submission and inventory requirement filing threshold of 10,000 lb (4,540 kg) therefore applies, per 40 CFR 370.20.

**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.

**Other U.S. Federal Regulations:** Regulations of the FDA under the Federal Food, Drug and Cosmetic Act are applicable when this material is used in pharmaceutical preparations. Under the Hazard Communication Standard (HCS), Section (b)(5)(ii) drugs are subject to labeling requirements by the FDA under the Federal Food, Drug and Cosmetic Act and are exempt from labeling provisions of the HCS; this section of the HCS exempts only labeling requirements and not requirements for a Safety Data Sheet for drugs.

**California Safe Drinking Water and Toxic Enforcement Act (Proposition 65):** No component of this product is on the California Proposition 65 Lists.

**CANADIAN REGULATIONS:**

**Canadian DSL Inventory Status:** This product regulated by the Therapeutic Products Programme (TPP) of Health Canada and so it 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.

**Canadian WHMIS Classification and Symbol:** The WHMIS Requirements of the Hazardous Products Act does not apply in respect of the advertising, sale or importation of any cosmetic, device, drug or food within the meaning of the Food and Drugs Act.

## 15. REGULATORY INFORMATION (Continued)

**EUROPEAN REGULATIONS:**

**Safety, Health, and Environmental Regulations/Legislation Specific for the Product:** When formulated in a finished medicinal product for human use, this material is subject to Directive 2001/83/EC and subsequent amendments to the directive.

**Chemical Safety Assessment:** No Data Available. The chemical safety assessment is required for some substances according to European Union Regulation (EC) 1907/2006, Article 14.

## 16. OTHER INFORMATION

**ANSI LABELING (Based on 129.1, Provided to Summarize Occupational Exposure Hazards): WARNING!** MAY BE HARMFUL IF ACCIDENTALLY INGESTED. LIMITED EVIDENCE OF HARM TO FETUS DURING PREGNANCY, BASED ON ANIMAL DATA. CONTAINS COMPOUND THAT CAN CAUSE LONG-TERM HARM TO AQUATIC ORGANISMS. COMBUSTIBLE IF EXPOSED TO HIGH TEMPERATURES. Do not take internally without prescription. Avoid unnecessary 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, 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, $CO_2$, 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.

**GLOBAL HARMONIZATION AND 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.

**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 OF COMPONENTS:

CLP Regulation (EC) 1272/2008

**Darifenacin Hydrobromide:** This is a self-classification:

Classification: Reproductive Toxicity Category 2, Eye Irritation Category 2A, Aquatic Chronic Toxicity Category 2

Hazard Statements: H361d: Suspected of damaging the unborn child. H319: Causes serious eye irritation. H412: Harmful to aquatic life with long-lasting effects.

**All Other Components:** An official classification for these substances has not been published nor is applicable.

67/548/EEC:

**Darifenacin Hydrobromide:** This is a self-classification:

Classification: Reproductive Toxicity Category 3, Dangerous for the Environment

Risk Phrases: R63: Possible risk of harm to the unborn child. R36: Irritating to eyes. R52/53: Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

**All Other Components:** An official classification for these substances has not been published nor is applicable.

**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:** New.



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