MATERIAL SAFETY DATA SHEET

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

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CHEMTREC (24 hours): 1-800-424-9300

Emergency telephone number:
ChemSafe (24 hours): +44 (0)208 762 8322

Material Name: Darifenacin Hydrobromide Modified Release Tablets (7.5 and 15 mg)

Trade Name: Not established
Chemical Family: Mixture
Intended Use: Pharmaceutical active for the treatment of overactive bladder

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Opadry orange	NOT ASSIGNED	Not listed	*
Magnesium stearate	557-04-0	209-150-3	*
Darifenacin hydrobromide	133099-07-7	Not listed	4.5-8.9

Ingredient	CAS Number	EU EINECS List	%
Opadry white	NOT ASSIGNED	Not listed	*
Opadry clear	NOT ASSIGNED	Not listed	*
Calcium phosphate dibasic, anhydrous	7757-93-9	231-826-1	*
Hypromellose	9004-65-3	Not listed	*
Water, purified	7732-18-5	231-791-2	*

Additional Information: * Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

3. HAZARDS IDENTIFICATION

Appearance: 7.5 mg: White film-coated tablets 15 mg: Orange
Signal Word: WARNING

Statement of Hazard: May be harmful if swallowed.
May cause eye irritation

Additional Hazard Information:
Short Term: May cause eye irritation; Harmful if swallowed (based on components) . Not a skin irritant ; Not a skin sensitizer (based on animal data) .
Known Clinical Effects: May cause effects similar to those seen in clinical use including dry mouth, blurred vision, constipation, and upset stomach.

EU Risk Phrases:

R52/53 - Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Note:

This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

4. FIRST AID MEASURES

Eye Contact:

Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.

Skin Contact:

Wash skin with soap and water. Remove contaminated clothing and shoes. This material may not be completely removed by conventional laundering. Consult professional laundry service. Do not home launder. If irritation occurs or persists, get medical attention.

Ingestion:

Get medical attention immediately. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

Inhalation:

Remove to fresh air. If not breathing, give artificial respiration. Get medical attention immediately.

5. FIRE FIGHTING MEASURES

Extinguishing Media:

Use carbon dioxide, dry chemical, or water spray.

Hazardous Combustion Products:

Emits toxic fumes of carbon monoxide, carbon dioxide, oxides of nitrogen and bromine-containing compounds

Fire Fighting Procedures:

Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear. Evacuate area and fight fire from a safe distance.

Fire / Explosion Hazards:

Not applicable

6. ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions:

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Measures for Cleaning / Collecting:

Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

Measures for Environmental Protections:

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

General Handling: If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing.

Storage Conditions: Keep container tightly closed when not in use.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Magnesium stearate

ACGIH Threshold Limit Value (TWA)	= 10 mg/m^3 TWA	except stearates of toxic metals
Australia TWA	= 10 mg/m^3 TWA	

Darifenacin hydrobromide

Pfizer OEL TWA-8 Hr:	0.025 mg/m^3

Analytical Method: Analytical method available for darifenacin. Contact Pfizer Inc for further information.

Engineering Controls: Engineering controls should be used as the primary means to control exposures.

Personal Protective Equipment:

Hands:	Not required for the normal use of this product. Wear protective gloves when working with large quantities.
Eyes:	Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.
Skin:	Not required for the normal use of this product. Wear protective clothing when working with large quantities.
Respiratory protection:	Not required for the normal use of this product. If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

9. PHYSICAL AND CHEMICAL PROPERTIES:

Physical State:	Film-coated tablets	**Color:**	7.5 mg: White 15 mg: Orange
Molecular Formula:	Mixture	**Molecular Weight:**	Mixture

10. STABILITY AND REACTIVITY

Stability: Stable
Conditions to Avoid: None known
Incompatible Materials: None known

Polymerization: Will not occur

11. TOXICOLOGICAL INFORMATION

General Information: There are no data for this formulation. The information included in this section describes the potential hazards of the individual ingredients.

Acute Toxicity: (Species, Route, End Point, Dose)

Magnesium stearate
Rat Oral LD50 > 2000 mg/kg
Rat Inhalation LC50 > 2000 mg/m^3

Darifenacin hydrobromide
Rat Dermal LD50 > 2000 mg/kg
Rat Oral LDmin. 100-200 mg/kg

Hypromellose
Rat Oral LD50 > 10,000 mg/kg

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Acute Toxicity Comments C Following intraperitoneal administration, the minimum lethal dose was between 50 and 100 mg/kg in mice and estimated at 50 mg/kg in rats (1 death at 50 mg/kg).

Irritation / Sensitization: (Study Type, Species, Severity)

Darifenacin hydrobromide
Skin Irritation Rabbit Non-irritating
Eye Irritation Rabbit Irritant
Skin Sensitization - GPMT Guinea Pig Negative

Subchronic Effects Oral toxicity studies of 1-, 3-, or 6-months were conducted in mice, rats or dogs. In addition to clinical signs consistent with the pharmacologic (anti-cholinergic) activity of the drug, increases in liver weight were frequently observed. In all cases, histological examinations were unremarkable and the increases in weight were attributed to adaptative metabolic changes.

Chronic Effects/Carcinogenicity In a one-year oral study in Beagles, darifenacin hydrobromide produced only eye and liver changes associated with it's pharmacologic properties. In two-year dietary studies in mice and rats, there was no evidence of carcinogenicity. In both studies effects on liver weight and histology were observed and were attributed to adaptive metabolic changes.

Reproductive Effects In fertility and embryo-fetal studies in rats and rabbits, there were no effects up to doses causing maternal toxicity. In a peri and postnatal development study in rats, the mid dose (10 mg/kg) induced no maternal toxicity, but a moderate decrease of the body weight of the pups and a slight delay in the grasping reflex and the appearance of incisors were observed. In the low-dose group (3 mg/kg), no maternal or pup toxicity was reported (NOAEL: 10 mg/kg-dams; 3 mg/kg-pups).

Mutagenicity Darifenacin (as tartrate salt) did not cause gene mutations in vivo or chromosomal aberration in vivo or in vitro.

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

12. ECOLOGICAL INFORMATION

Environmental Overview: This formulation has not been tested as a whole, the following apply to component substance(s): In the environment, the active ingredient in this formulation is expected to remain in water or migrate through the soil to groundwater Harmful effects to aquatic organisms could occur.

Mobility, Persistence and Degradability: The active ingredient in this formulation is expected to remain in water or migrate through soil There are no data on the degradability of this material.

Bioaccumulation and Toxicity: Acute toxicity to aquatic organisms could occur. Long-term adverse effects to aquatic organisms are possible. See aquatic toxicity data, below.

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Darifenacin hydrobromide
Green Algae IC50/48h (NPDES) 2.2
Skeletonema Algae IC50/96h (NPDES) 0.7
Daphnia magna LC50/48h (NPDES) 2.3
Mysid Shrimp LC50/48h (NPDES) 2.1
Oyster embryo LC50/48h (NPDES) 0.44

13. DISPOSAL CONSIDERATIONS

Disposal Procedures: Dispose of waste in accordance with all applicable laws and regulations.

14. TRANSPORT INFORMATION

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

EU Risk Phrases:

R52/53 - Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

EU Safety Phrases:

S57 - Use appropriate containment to avoid environmental contamination.

OSHA Label:
WARNING
May be harmful if swallowed.
May cause eye irritation

Canada - WHMIS: Classifications

WHMIS hazard class:
Class D, Division 2, and Subdivision B.

Calcium phosphate dibasic, anhydrous

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	231-826-1

Hypromellose

Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4

Magnesium stearate

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	209-150-3

Water, purified

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	231-791-2

16. OTHER INFORMATION

Reasons for Revision: Updated Section 3 - Hazard Identification. Updated Section 6 - Accidental Release Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information. Updated Section 13 - Disposal Considerations. Updated Section 15 - Regulatory Information.

Prepared by: Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety

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End of Safety Data Sheet