

1. Identification

Product identifier	Darifenacin Chiral Peak ID Mixture		
Other means of identification			
Catalog number	1164211		
Recommended use	Specified quality tests and assay use only.		
Recommended restrictions	Not for use as a drug. Not for administration to humans or animals.		
Manufacturer/Importer/Supplier/Distributor information			
Manufacturer			
Company name	U. S. Pharmacopeia		
Address	12601 Twinbrook Parkway Rockville MD 20852-1790 United States		
Telephone	RS Technical Services	301-816-8129	
Website	www.usp.org		
E-mail	RSTECH@usp.org		
Emergency phone number	CHEMTREC within US & Canada	1-800-424-9300	
	CHEMTREC outside US & Canada	+1 703-527-3887	

2. Hazard(s) identification

Physical hazards	Not classified.		
Health hazards	Acute toxicity, oral	Category 4	
	Serious eye damage/eye irritation	Category 2A	
Environmental hazards	Not classified.		
OSHA defined hazards	Not classified.		
Label elements			



Signal word	Warning		
Hazard statement	Harmful if swallowed. Causes serious eye irritation.		
Precautionary statement			
Prevention	Wash thoroughly after handling. Wear eye/face protection.		
Response	If swallowed: Call a poison center/doctor if you feel unwell. Rinse mouth. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.		
Storage	Not available.		
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.		
Hazard(s) not otherwise classified (HNOC)	Not classified.		
Other hazards which do not result in classification	This product is supplied in a small quantity which does not constitute a combustible dust hazard. The physical properties of this material indicate that in large quantities accumulated dust may be hazardous.		

3. Composition/information on ingredients

Mixture			
Hazardous components			
Chemical name	Common name and synonyms	CAS number	%
Darifenacin Hydrobromide		133099-07-7	>98

Non-hazardous components

Chemical name	Common name and synonyms	CAS number	%
(R)-2-{1-[2-(2,3-Dihydrobenzofuran-5-yl)ethyl]-3-pyrrolidinyl}-2,2-diphenylacetamide hydrobromide		1092800-15-1	<2

4. First-aid measures

Inhalation	If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Call a physician if symptoms develop or persist.
Skin contact	Rinse skin with water/shower. Get medical attention if irritation develops and persists.
Eye contact	Rinse with water. Get medical attention if irritation develops and persists.
Ingestion	Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately.
Most important symptoms/effects, acute and delayed	Irritation of eyes and mucous membranes.
Indication of immediate medical attention and special treatment needed	Provide general supportive measures and treat symptomatically.
General information	Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

5. Fire-fighting measures

Suitable extinguishing media	Water. Foam. Dry chemical or CO2. Use fire-extinguishing media appropriate for surrounding materials.
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	Explosion hazard: Avoid generating dust; fine dust dispersed in air in sufficient concentrations and in the presence of an ignition source is a potential dust explosion hazard.
Special protective equipment and precautions for firefighters	Wear suitable protective equipment.
Fire-fighting equipment/instructions	Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Wear appropriate personal protective equipment. Avoid inhalation of dust from the spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. For personal protection, see section 8 of the SDS.
Methods and materials for containment and cleaning up	For waste disposal, see section 13 of the SDS. Avoid the generation of dusts during clean-up. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination.

7. Handling and storage

Precautions for safe handling	As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Avoid significant deposits of material, especially on horizontal surfaces, which may become airborne and form combustible dust clouds and may contribute to secondary explosions. Combustible dust clouds may be created where operations produce fine material (dust).
Conditions for safe storage, including any incompatibilities	Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

8. Exposure controls/personal protection

Exposure limit values

Industrial Use Components

Type	Value
Darifenacin Hydrobromide (CAS 133099-07-7)	TWA 0.025 mg/m3

Biological limit values	No biological exposure limits noted for the ingredient(s).
Appropriate engineering controls	Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials. Local exhaust ventilation such as a laboratory fume hood or other vented enclosure is recommended, particularly for grinding, crushing, weighing, or other dust-generating procedures.
Individual protection measures, such as personal protective equipment	
Eye/face protection	Safety glasses with sideshields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.
Skin protection	
Hand protection	Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic nonlatex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.
Other	For handling of laboratory scale quantities, a cloth lab coat is recommended. Where significant quantities are handled, work clothing may be necessary to prevent take-home contamination.
Respiratory protection	Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).
General hygiene considerations	Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

Appearance	White powder.
Physical state	Solid.
Form	Powder.
Odor	Not available.
Odor threshold	Not available.
pH	Not available.
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not applicable.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	Not available.
Vapor density	Not available.
Relative density	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.

10. Stability and reactivity

Reactivity	Not available.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Contact with incompatible materials.
Incompatible materials	Not available.

Hazardous decomposition products

NOx. Br-. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

11. Toxicological information**Information on likely routes of exposure**

Ingestion	Harmful if swallowed.
Inhalation	Classification not possible.
Skin contact	Classification not possible.
Eye contact	Causes serious eye irritation.

Symptoms related to the physical, chemical, and toxicological characteristics

Component: Anticholinergics: Dry mouth, throat, nose, skin, or eyes. Flushing. Decreased sweating. Fever. Decreased urination. Fast heartbeat. Headache. Dizziness. Drowsiness. Unsteadiness. Weakness. Restlessness. Confusion. Memory problems. Hallucinations. Insomnia. Seizures. Slurred speech. Blurred vision. Dilated pupils. Decreased sexual interest and ability. Nausea. Indigestion. Constipation. Diarrhea. Difficulty swallowing.

Delayed and immediate effects of exposure

Component: Anticholinergics: Dependence. High blood pressure. Hyperthermia. Tachycardia. Respiratory depression. Central nervous system excitation. Dehydration. Coma. Death.

Medical conditions aggravated by exposure

Anticholinergics: Heart disease. Tachycardia. Hyperthyroidism. High blood pressure. Myasthenia gravis. Gastrointestinal reflux or obstruction. Ulcerative colitis. Paralytic ileus. Urinary retention or obstruction. Glaucoma. Kidney or liver impairment. Bleeding disorders. Prostate enlargement. Epilepsy. Porphyria.

Acute toxicity

Harmful if swallowed.

Components**Species****Test Results**

Darifenacin Hydrobromide (CAS 133099-07-7)

Dermal

LD50

Rat

> 2000

Skin corrosion/irritation

Classification not possible.

Serious eye damage/eye irritation

Causes serious eye irritation.

Local effects

Darifenacin Hydrobromide

Irritancy test
Result: Irritant.
Species: Rabbit
Organ: Eye.
Irritancy test
Result: Non-irritant.
Species: Rabbit
Organ: Skin.

Respiratory or skin sensitization**Respiratory sensitization**

Classification not possible.

Skin sensitization

Classification not possible.

Skin sensitization

Darifenacin Hydrobromide

Sensitization test (GPMT)
Result: Non-sensitizing.
Species: Guinea pig

Germ cell mutagenicity

Classification not possible.

Mutagenicity

Darifenacin Hydrobromide

Chromosomal aberration study
Result: Negative.
Mammalian cell mutagenicity test in CHO cells
Result: Negative.
Reverse mutation assay- Ames test
Result: Negative.

Carcinogenicity

Classification not possible. This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

Darifenacin Hydrobromide

Carcinogenicity study (dietary)
Result: No evidence of carcinogenicity in rats and mice.
Test Duration: 2 years

Reproductive toxicity

Classification not possible.

Reproductivity

Darifenacin Hydrobromide

Reproductivity study
Result: In fertility and embryo-fetal studies in rats and rabbits, there were no effects.

Specific target organ toxicity - single exposure Classification not possible.

Specific target organ toxicity - repeated exposure Classification not possible.

Aspiration hazard Not classified.

12. Ecological information

Ecotoxicity

Product		Species	Test Results
Darifenacin Chiral Peak ID Mixture			
Aquatic			
Crustacea	EC50	Daphnia	2.3469 mg/l, 48 hours estimated
Components		Species	Test Results
Darifenacin Hydrobromide (CAS 133099-07-7)			
Aquatic			
Crustacea	EC50	Daphnia	2.3 mg/l, 48 hours

* Estimates for product may be based on additional component data not shown.

Persistence and degradability Not available.

Bioaccumulative potential Not available.

Mobility in soil Not available.

Other adverse effects Not available.

13. Disposal considerations

Disposal instructions	Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste.
Local disposal regulations	Dispose in accordance with all applicable regulations.
Hazardous waste code	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
Waste from residues / unused products	Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
Contaminated packaging	Since emptied containers may retain product residue, follow label warnings even after container is emptied. Empty containers should be taken to an approved waste handling site for recycling or disposal.

14. Transport information

DOT

UN number	UN3077
UN proper shipping name	Environmentally hazardous substance, n.o.s. (Darifenacin Hydrobromide)
Transport hazard class(es)	
Class	9
Subsidiary risk	-
Packing group	III

IATA

UN number	UN3077
UN proper shipping name	Environmentally hazardous substance, n.o.s. (Darifenacin Hydrobromide)
Transport hazard class(es)	
Class	9
Subsidiary risk	-
Packing group	III
Other information	
Passenger and cargo aircraft	Allowed.
Cargo aircraft only	Allowed.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not available.

**General information**

It is the shipper's responsibility to determine the correct transport classification at the time of shipment.

15. Regulatory information**US federal regulations**

This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.
One or more components are not listed on TSCA.

Superfund Amendments and Reauthorization Act of 1986 (SARA)**Hazard categories**

Immediate Hazard - Yes
Delayed Hazard - No
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical

No

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations**Safe Drinking Water Act (SDWA)**

Not regulated.

Food and Drug Administration (FDA)

Not regulated.

US state regulations**US. California Proposition 65**

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date 10-16-2015
Revision date 05-10-2016
Version # 02

Further information

Refer to NFPA 654, Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids, for safe handling.

Disclaimer

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Revision Information

Hazard(s) identification: Response

Composition / Information on Ingredients: Ingredients

Physical & Chemical Properties: Multiple Properties

Toxicological information: Medical conditions aggravated by exposure

Toxicological information: Symptoms related to the physical, chemical, and toxicological characteristics

Toxicological information: Delayed and immediate effects of exposure

GHS: Classification