


## 1. Identification

<b>Product identifier</b>	<b>Dronedarone Hydrochloride</b>	
<b>Other means of identification</b>		
<b>Catalog number</b>	1228530	
<b>Chemical name</b>	N-{2-butyl-3-[4-(3-dibutylaminopropoxy)benzoyl]benzofuran-5-yl} methanesulfonamide hydrochloride	
<b>Recommended use</b>	Specified quality tests and assay use only.	
<b>Recommended restrictions</b>	Not for use as a drug. Not for administration to humans or animals.	
<b>Manufacturer/Importer/Supplier/Distributor information</b>		
<b>Manufacturer</b>		
<b>Company name</b>	U. S. Pharmacopeia	
<b>Address</b>	12601 Twinbrook Parkway Rockville MD 20852-1790 United States	
<b>Telephone</b>	RS Technical Services	301-816-8129
<b>Website</b>	www.usp.org	
<b>E-mail</b>	RSTECH@usp.org	
<b>Emergency phone number</b>	CHEMTREC within US & Canada	1-800-424-9300
	CHEMTREC outside US & Canada	+1 703-527-3887

## 2. Hazard(s) identification

<b>Note</b>	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.	
<b>Physical hazards</b>	Not classified.	
<b>Health hazards</b>	Serious eye damage/eye irritation	Category 2A
	Reproductive toxicity	Category 1B
	Specific target organ toxicity, repeated exposure	Category 1 (cardiovascular system, liver)
<b>Environmental hazards</b>	Not classified.	
<b>OSHA defined hazards</b>	Not classified.	
<b>Label elements</b>		
<b>Signal word</b>	Danger	
<b>Hazard statement</b>	Causes serious eye irritation. May damage fertility or the unborn child. Causes damage to organs (cardiovascular system, liver) through prolonged or repeated exposure.	
<b>Precautionary statement</b>		
<b>Prevention</b>	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wash thoroughly after handling. Wear protective gloves/protective clothing/eye protection/face protection.	
<b>Response</b>	If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If exposed or concerned: Get medical advice/attention. If eye irritation persists: Get medical advice/attention.	
<b>Storage</b>	Store locked up.	
<b>Disposal</b>	Dispose of contents/container in accordance with local/regional/national/international regulations.	
<b>Hazard(s) not otherwise classified (HNOC)</b>	Not classified.	

Other hazards which do not result in classification None known.

### 3. Composition/information on ingredients

#### Substance

Chemical name	Common name and synonyms	CAS number	%
Dronedarone Hydrochloride		141625-93-6	100

### 4. First-aid measures

<b>Inhalation</b>	Move to fresh air. Call a physician if symptoms develop or persist.
<b>Skin contact</b>	Rinse skin with water/shower. Get medical attention if irritation develops and persists.
<b>Eye contact</b>	Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists.
<b>Ingestion</b>	Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately.
<b>Most important symptoms/effects, acute and delayed</b>	Irritation of eyes and mucous membranes. Gastrointestinal disturbances. Heart rhythm abnormalities.
<b>Indication of immediate medical attention and special treatment needed</b>	Provide general supportive measures and treat symptomatically. Administer activated charcoal as an aqueous slurry, unless contraindicated. Provide assisted ventilation if necessary. Maintain adequate hydration. For hypokalemia, administer potassium supplements. For hypotension, administer standard crystalloid bolus and vasopressors if necessary. For AV block and QT prolongation, treat with magnesium, isoproterenol, and/or electrical pacing if needed. For bradycardia, administer isoproterenol and epinephrine and cardiac pacing if needed.. Antidysrhythmics are contraindicated. [TOXINZ]
<b>General information</b>	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

<b>Suitable extinguishing media</b>	Use fire-extinguishing media appropriate for surrounding materials. Water. Foam. Dry chemical or CO2.
<b>Unsuitable extinguishing media</b>	None known.
<b>Specific hazards arising from the chemical</b>	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.
<b>Special protective equipment and precautions for firefighters</b>	Wear suitable protective equipment.
<b>Fire-fighting equipment/instructions</b>	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.
<b>Specific methods</b>	Use standard firefighting procedures and consider the hazards of other involved materials.

### 6. Accidental release measures

<b>Personal precautions, protective equipment and emergency procedures</b>	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. Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Avoid inhalation of dust from the spilled material. Wear appropriate personal protective equipment.
<b>Methods and materials for containment and cleaning up</b>	Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid the generation of dusts during clean-up. For waste disposal, see section 13 of the SDS. Clean surface thoroughly to remove residual contamination.

### 7. Handling and storage

<b>Precautions for safe handling</b>	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. Combustible dust clouds may be created where operations produce fine material (dust). Avoid significant deposits of material, especially on horizontal surfaces, which may become airborne and form combustible dust clouds and may contribute to secondary explosions.
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**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 Material**

**Type**

**Value**

Dronedarone Hydrochloride  
(CAS 141625-93-6)

TWA

0.1 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 to off-white powder.

#### Physical state

Solid.

#### Form

Powder.

### Odor

Not available.

### Odor threshold

Not available.

### pH

Not available.

### Melting point/freezing point

278.6 - 293 °F (137 - 145 °C)

### 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.

### Solubility in water

Practically insoluble in water.

### Partition coefficient (n-octanol/water)

4.63 (at pH 7)

<b>Auto-ignition temperature</b>	572 °F (300 °C)
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not available.
<b>Other information</b>	
<b>Chemical family</b>	Benzofuran.
<b>Dust explosion properties</b>	
<b>Minimum ignition energy (MIE) - dust cloud</b>	< 10 mJ (High risk of dust explosion).
<b>Molecular formula</b>	C31H44N2O5S . HCl
<b>Molecular weight</b>	593.26
<b>Solubility (other)</b>	Soluble in dimethylsulfoxide, in methylene chloride, and in methanol.

## 10. Stability and reactivity

<b>Reactivity</b>	Not available.
<b>Chemical stability</b>	Material is stable under normal conditions.
<b>Possibility of hazardous reactions</b>	No dangerous reaction known under conditions of normal use.
<b>Conditions to avoid</b>	Ignition sources.
<b>Incompatible materials</b>	Strong oxidizing agents.
<b>Hazardous decomposition products</b>	NO <sub>x</sub> , SO <sub>x</sub> , HCl. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

## 11. Toxicological information

### Information on likely routes of exposure

<b>Ingestion</b>	Based on available data, the classification criteria are not met.
<b>Inhalation</b>	Due to lack of data the classification is not possible.
<b>Skin contact</b>	Due to lack of data the classification is not possible.
<b>Eye contact</b>	Causes serious eye irritation.

**Symptoms related to the physical, chemical, and toxicological characteristics** Nausea. Vomiting. Diarrhea. Abdominal pain. Indigestion. Weakness. Fatigue. Skin rash. Itching. Shortness of breath.

**Delayed and immediate effects of exposure** Liver injury. Arrhythmias. Prolonged QT interval. Bradycardia. Heart failure. Interstitial lung disease.

**Medical conditions aggravated by exposure** Heart failure. Cardiac conduction disorders. Bradycardia. Permanent atrial fibrillation. Liver impairment. Kidney impairment.

### Acute toxicity

Product	Species	Test Results
Dronedarone Hydrochloride (CAS 141625-93-6)		
<b>Acute</b>		
<b>Oral</b>		
LD50	Mouse	> 2000 mg/kg
	Rat	> 2000 mg/kg

**Skin corrosion/irritation** Based on available data, the classification criteria are not met.

**Serious eye damage/eye irritation** Causes serious eye irritation.

### Local effects

Eye irritancy  
Result: Irritant.  
Species: Rabbit  
Skin irritancy  
Result: Non-irritant.  
Species: Rabbit

### Respiratory or skin sensitization

**Respiratory sensitization** Due to lack of data the classification is not possible.

**Skin sensitization** Due to lack of data the classification is not possible.

**Germ cell mutagenicity** Due to lack of data the classification is not possible.  
Data from germ cell mutagenicity tests were not found.

### Mutagenicity

Ames test  
Result: Negative.  
HPRT  
Result: Equivocal.  
In vitro chromosomal aberration assay in human lymphocytes  
Result: Negative.  
In vivo micronucleus test  
Result: Negative.  
Unscheduled DNA synthesis assay  
Result: Negative.

### Carcinogenicity

Based on available data, the classification criteria are not met.  
This material is not considered to be a carcinogen by IARC, NTP, or OSHA.

300 mg/kg/day Long-term carcinogenicity study, (8 times the recommended human dose)  
Result: Increased incidence of histiocytic sarcomas (males) and mammary adenocarcinomas (females)  
Species: Mouse  
70 mg/kg/day Long-term carcinogenicity study, (5 times the recommended human dose)  
Result: Increased incidence of hemangiomas  
Species: Rat

### Reproductive toxicity

May damage fertility or the unborn child.

#### Reproductivity

20 mg/kg/day Reproductivity and development, administered during gestation.  
Result: Skeletal malformation in offspring.  
Species: Rabbit  
>= 80 mg/kg/day Reproductivity and development, administered orally during gestation.  
Result: External, visceral, and skeletal malformation in offspring.  
Species: Rat  
Fertility study  
Result: NOEL for female fertility = 30 mg/kg/day  
Species: Rat

### Specific target organ toxicity - single exposure

Based on available data, the classification criteria are not met.

### Specific target organ toxicity - repeated exposure

Causes damage to organs (cardiovascular system, liver) through prolonged or repeated exposure.

### Aspiration hazard

Based on available data, the classification criteria are not met.

## 12. Ecological information

### Ecotoxicity

Product		Species	Test Results
Dronedarone Hydrochloride (CAS 141625-93-6)			
<b>Aquatic</b>			
<i>Acute</i>			
Crustacea	EC50	Daphnia magna	> 0.43 mg/l, 48 hours
Fish	LC50	Oncorhynchus mykiss	0.45 mg/l, 96 hours

### Persistence and degradability

Not readily biodegradable.

### 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

Not available.

### Hazardous waste code

Not regulated.

### 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**

Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

**14. Transport information****DOT**

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

**IATA**

**UN number** UN3077  
**UN proper shipping name** Environmentally hazardous substance, solid, n.o.s. (Dronedarone Hydrochloride)  
**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.

**DOT; IATA****15. Regulatory information**

**US federal regulations** CERCLA/SARA Hazardous Substances - Not applicable.

One or more components are not listed on TSCA.

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

**Hazard categories** Immediate Hazard - Yes  
 Delayed Hazard - Yes  
 Fire Hazard - Yes  
 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**

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.

**US. California Proposition 65**

Not Listed.

## 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

<b>Issue date</b>	08-21-2015
<b>Revision date</b>	09-04-2015
<b>Version #</b>	02
<b>Further information</b>	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.
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