

## 1. Identification

Product identifier	Acebutolol Hydrochloride	
Other means of identification		
Catalog number	1000601	
CAS number	34381-68-5	
Chemical name	Butanamide, N-[3-acetyl-4-[2-hydroxy-3-[(1-methylethyl)-amino]propoxy]phenyl]-, monohydrochloride, (+/-)-	
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

<b>Physical hazards</b>	Not classified.	
<b>Health hazards</b>	Serious eye damage/eye irritation	Category 2A
	Specific target organ toxicity, single exposure	Category 1 (cardiovascular system)
<b>Environmental hazards</b>	Not classified.	
<b>OSHA defined hazards</b>	Not classified.	

### Label elements



<b>Signal word</b>	Danger	
<b>Hazard statement</b>	Causes serious eye irritation. Causes damage to organs (cardiovascular system).	
<b>Precautionary statement</b>		
<b>Prevention</b>	Do not breathe dust. Wash thoroughly after handling. Wear 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 eye irritation persists: Get medical advice/attention. If exposed: Call a poison center/doctor.	
<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>	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>Supplemental information</b>	Pharmacologically active material.	

### 3. Composition/information on ingredients

#### Substance

Chemical name	Common name and synonyms	CAS number	%
Acebutolol Hydrochloride		34381-68-5	100

### 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	Wash off with soap and water. Get medical attention if irritation develops and persists.
Eye contact	Immediately flush eyes with plenty of water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.
Ingestion	Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately.
Most important symptoms/effects, acute and delayed	Cardiovascular effects. Pharmacologically active material. Occupational exposure may cause physiological effects.
Indication of immediate medical attention and special treatment needed	Provide general supportive measures and treat symptomatically. For beta-adrenergic blockers: Treatment may include the following: Do NOT induce vomiting. Administer activated charcoal as a slurry and perform gastric lavage to decrease absorption. Gastric lavage may increase vagal tone. Maintain an open airway and assist ventilation if necessary. Perform an early echocardiographic evaluation. For mild hypotension, administer IV fluids. If severe, administer IV glucagon, calcium, or catecholamines (dopamine, norepinephrine, epinephrine). Concurrent high-dose insulin euglycemia therapy may allow for a decrease in the dose of catecholamine. For bradycardia, administer IV atropine, glucagon, and isoproterenol. Cardiac pacing may also be needed. Sodium bicarbonate may be helpful for dysrhythmias and conduction defects. For bronchospasm, administer nebulized bronchodilators. Systemic corticosteroids may also be beneficial. For seizures, administer a benzodiazepine (diazepam or lorazepam) intravenously. Muscle relaxants and artificial ventilation may also be required. For hypoglycemia, administer glucose or glucagon.
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.
General fire hazards	No unusual fire or explosion hazards noted.

### 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.
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.
Environmental precautions	Avoid discharge into drains, water courses or onto the ground.

## 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). Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential.

### 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

### Occupational exposure limits

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

### Exposure limit values

Industrial Use Material	Type	Value
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Acebutolol Hydrochloride (CAS 34381-68-5)	TWA	400 micrograms/m3
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### Biological limit values

No biological exposure limits noted for the ingredient(s).

### Appropriate engineering controls

For laboratory operations, use local exhaust ventilation or a ventilated enclosure for high energy operations such as particle sizing. Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred.

### Individual protection measures, such as personal protective equipment

#### Eye/face protection

Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.

#### Skin protection

##### Hand protection

Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent.

##### Other

Train employees in proper gowning and degowning practices. Wear lab coat. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do not wear protective garments in common areas (e.g., cafeterias) or out-of-doors.

#### Respiratory protection

Respirators are generally not required for laboratory operations. Use a tight-fitting full-face respirator with HEPA filters for spill cleanup. Choose respiratory protection appropriate to the task and the level of existing engineering controls.

#### Thermal hazards

Wear appropriate thermal protective clothing, when necessary.

### General hygiene considerations

Handling practices in this SDS are recommendations for laboratory use of reference standards. Procedures for any other uses or quantities should be determined after an appropriate assessment.

## 9. Physical and chemical properties

### Appearance

Appearance descriptions are general information and not specific to any USP lot.

#### Physical state

Solid.

#### Form

Powder.

#### Color

White. Off-white.

### Odor

Odorless.

### Odor threshold

Not available.

### pH

Not available.

### Melting point/freezing point

285.8 - 291.2 °F (141 - 144 °C)

### Initial boiling point and boiling range

Not available.

### Flash point

Not available.

### Evaporation rate

Not available.

**Flammability (solid, gas)** Not available.

**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(ies)**

**Solubility (water)** Freely soluble.

**Solubility (other)** Methanol: Soluble.  
Acetone: Very slightly soluble.  
Methylene chloride: Very slightly soluble.  
Ether: Practically insoluble.  
Ethanol: Soluble.

**Auto-ignition temperature** Not available.

**Decomposition temperature** Not available.

**Viscosity** Not available.

**Other information**

**Chemical family** Propanolamine.

**Dust explosion properties**

**Kst** 211 bar.m/s

**Minimum ignition energy (MIE) - dust layer** 1 - 3 mJ

**Molecular formula** C18H28N2O4 . HCl

**Molecular weight** 372.89

**pH in aqueous solution** 4.5 - 7 Solution: 1%

## 10. Stability and reactivity

**Reactivity** The product is stable and non-reactive under normal conditions of use, storage and transport.

**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** Strong oxidizing agents.

**Hazardous decomposition products** NOx. Cl-. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

## 11. Toxicological information

**Information on likely routes of exposure**

**Inhalation** Knowledge about health hazard is incomplete.

**Skin contact** Knowledge about health hazard is incomplete.

**Eye contact** Causes serious eye irritation.

**Ingestion** Based on information from therapeutic use, this material may cause: Cardiovascular effects.

**Symptoms related to the physical, chemical, and toxicological characteristics** Beta-adrenergic blockers: Gastrointestinal disturbances. Headache. Mood or mental changes. Drowsiness. Weakness. Insomnia. Nervousness. Visual disturbances. Swelling of feet or legs. Muscle, joint, or chest pain. Seizures. Coma. Cardiovascular effects. Respiratory depression.

**Information on toxicological effects**

**Acute toxicity**

Product	Species	Test Results
Acebutolol Hydrochloride (CAS 34381-68-5)		
Oral		
LD50	Mouse	4050 mg/kg
	Rat	6620 mg/kg
Skin corrosion/irritation	Knowledge about health hazard is incomplete.	
Serious eye damage/eye irritation	Causes serious eye irritation.	
Local effects		
Eye irritation		
Result: Irritant.		
Species: Rabbit		
Respiratory or skin sensitization		
Respiratory sensitization	Knowledge about health hazard is incomplete.	
Skin sensitization	Knowledge about sensitization hazard is incomplete.	
Germ cell mutagenicity	Knowledge about mutagenicity is incomplete.	
Mutagenicity		
Ames test		
Result: Negative.		
Micronucleus test		
Result: Negative.		
Carcinogenicity	Knowledge about carcinogenicity is incomplete.	
0 - 300 mg/kg/day Carcinogenicity		
Result: Not carcinogenic.		
Species: Mouse		
Test Duration: 87 weeks		
0 - 300 mg/kg/day Carcinogenicity		
Result: Not carcinogenic.		
Species: Rat		
Test Duration: 78 weeks		
IARC Monographs. Overall Evaluation of Carcinogenicity		
Not listed.		
OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)		
Not regulated.		
US. National Toxicology Program (NTP) Report on Carcinogens		
Not listed.		
Reproductive toxicity	Based on available data, the classification criteria are not met. Some beta-adrenergic blocking agents have been reported to cause fetal and neonatal bradycardia, hypotension, and hypoglycemia when administered during pregnancy, and may also be associated with fetal growth retardation.	
Reproductivity		
240 mg/kg/day Two-generation reproductive toxicity		
Result: No significant impact on reproductive performance or fertility.		
Species: Rat		
< 135 mg/kg/day Reproductivity		
Result: Slight fetal growth retardation due to maternal toxicity. Not teratogenic.		
Species: Rabbit		
< 630 mg/kg/day Reproductivity		
Result: Not teratogenic.		
Species: Rat		
Specific target organ toxicity - single exposure	Causes damage to organs (cardiovascular system).	
Specific target organ toxicity - repeated exposure	Knowledge about health hazard is incomplete.	
Aspiration hazard	Based on available data, the classification criteria are not met.	
Further information	Pharmacologically active material. Occupational exposure may cause physiological effects.	

## 12. Ecological information

### Ecotoxicity

Product	Species	Test Results
Acebutolol Hydrochloride (CAS 34381-68-5)		
<b>Aquatic</b>		
Crustacea	EC50	Daphnia
		> 100 mg/l, 48 hours
<b>Persistence and degradability</b>	No data is available on the degradability of this product.	
<b>Bioaccumulative potential</b>	No data available.	
<b>Mobility in soil</b>	No data available.	
<b>Other adverse effects</b>	No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.	

## 13. Disposal considerations

<b>Disposal instructions</b>	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.
<b>Local disposal regulations</b>	Dispose in accordance with all applicable regulations.
<b>Hazardous waste code</b>	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
<b>Waste from residues / unused products</b>	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).
<b>Contaminated packaging</b>	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

Not regulated as dangerous goods.

### IATA

Not regulated as dangerous goods.

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

**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.

### TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

### CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

### SARA 304 Emergency release notification

Not regulated.

### OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

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

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

### SARA 302 Extremely hazardous substance

Not listed.

**SARA 311/312 Hazardous chemical** Yes

**SARA 313 (TRI reporting)**

Not regulated.

**Other federal regulations****Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List**

Not regulated.

**Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)**

Not regulated.

**Safe Drinking Water Act (SDWA)**

Not regulated.

**US state regulations**

This product does not contain a chemical known to the State of California to cause cancer, birth defects or other reproductive harm.

**International Inventories**

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
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)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	Yes
New Zealand	New Zealand Inventory	Yes
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** 02-03-2011**Revision date** 10-02-2018**Version #** 03**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.

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