

## SAFETY DATA SHEETS

**This SDS packet was issued with item:**

078937582

N/A

# Bupropion Hydrochloride Extended Release Tablets USP 150 mg & 300 mg

## Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations  
Date of Issue: 06/21/2018

Version: 1.0

### SECTION 1: IDENTIFICATION

#### 1.1. Product Identifier

**Product Form:** Mixture

**Product Name:** Bupropion Hydrochloride Extended Release Tablets USP 150 mg & 300 mg

#### 1.2. Intended Use of the Product

**Use of the Substance/Mixture:** Pharmaceutical.

#### 1.3. Name, Address, and Telephone of the Responsible Party

##### Company

Accord Healthcare, Inc.

1009 Slater Road

Suite 210-B

Durham, NC 27703

USA

Telephone: 1-919-941-7880

Fax- 1-919-941-7881

[www.accord-healthcare.com](http://www.accord-healthcare.com)

#### 1.4. Emergency Telephone Number

**Emergency Number** : 1-800-424-9300  
Call CHEMTREC Day or Night

### SECTION 2: HAZARDS IDENTIFICATION

*This product is a drug, as defined by the US Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) It is in solid, final form for direct administration to the patient. Therefore, it is exempt from labeling, as defined in the 29 CFR 1910.1200(b)(5)(iii).*

### SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

*This product is a drug, as defined by the US Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) It is in solid, final form for direct administration to the patient. Therefore, it is exempt from the US 2012 Hazard Communication Standard, as defined in the 29 CFR 1910.1200(b)(6)(vii).*

### SECTION 4: FIRST AID MEASURES

#### 4.1. Description of First-aid Measures

**First-aid Measures General:** Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

**First-aid Measures After Inhalation:** When symptoms occur: go into open air and ventilate suspected area. Obtain medical attention if breathing difficulty persists.

**First-aid Measures After Skin Contact:** Remove contaminated clothing. Drench affected area with water for at least 15 minutes. Obtain medical attention if irritation develops or persists.

**First-aid Measures After Eye Contact:** Rinse cautiously with water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention.

**First-aid Measures After Ingestion:** Rinse mouth. Do NOT induce vomiting. Obtain medical attention.

#### 4.2. Most Important Symptoms and Effects Both Acute and Delayed

**Symptoms/Injuries:** Harmful if swallowed.

**Symptoms/Injuries After Inhalation:** Prolonged exposure may cause irritation.

**Symptoms/Injuries After Skin Contact:** Prolonged exposure may cause skin irritation.

**Symptoms/Injuries After Eye Contact:** May cause slight irritation to eyes.

**Symptoms/Injuries After Ingestion:** This material is harmful orally and can cause adverse health effects or death in significant amounts.

**Chronic Symptoms:** None expected under normal conditions of use.

#### 4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

If exposed or concerned, get medical advice and attention. If medical advice is needed, have product container or label at hand.

### SECTION 5: FIRE-FIGHTING MEASURES

#### 5.1. Extinguishing Media

**Suitable Extinguishing Media:** Water spray, dry chemical, foam, carbon dioxide.

**Unsuitable Extinguishing Media:** Do not use a heavy water stream. Use of heavy stream of water may spread fire.

#### 5.2. Special Hazards Arising From the Substance or Mixture

**Fire Hazard:** In powdered form: combustible dust.

**Explosion Hazard:** Dust explosion hazard in air.

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**Reactivity:** Hazardous reactions will not occur under normal conditions.

### 5.3. Advice for Firefighters

**Precautionary Measures Fire:** Exercise caution when fighting any chemical fire.

**Firefighting Instructions:** Use water spray or fog for cooling exposed containers.

**Protection During Firefighting:** Do not enter fire area without proper protective equipment, including respiratory protection.

**Hazardous Combustion Products:** Nitrogen oxides. Carbon oxides (CO, CO<sub>2</sub>).

## SECTION 6: ACCIDENTAL RELEASE MEASURES

### 6.1. Personal Precautions, Protective Equipment and Emergency Procedures

**General Measures:** Avoid breathing dust. Avoid all contact with skin, eyes, or clothing.

#### 6.1.1. For Non-Emergency Personnel

**Protective Equipment:** Use appropriate personal protective equipment (PPE).

**Emergency Procedures:** Evacuate unnecessary personnel.

#### 6.1.2. For Emergency Personnel

**Protective Equipment:** Equip cleanup crew with proper protection.

**Emergency Procedures:** Upon arrival at the scene, a first responder is expected to recognize the presence of dangerous goods, protect oneself and the public, secure the area, and call for the assistance of trained personnel as soon as conditions permit. Ventilate area.

### 6.2. Environmental Precautions

Prevent entry to sewers and public waters.

### 6.3. Methods and Materials for Containment and Cleaning Up

**For Containment:** Contain solid spills with appropriate barriers and prevent migration and entry into sewers or streams.

**Methods for Cleaning Up:** Clean up spills immediately and dispose of waste safely. Recover the product by vacuuming, shoveling or sweeping. Transfer spilled material to a suitable container for disposal. Contact competent authorities after a spill.

### 6.4. Reference to Other Sections

See Section 8 for exposure controls and personal protection and Section 13 for disposal considerations.

## SECTION 7: HANDLING AND STORAGE

### 7.1. Precautions for Safe Handling

**Additional Hazards When Processed:** Accumulation and dispersion of dust with an ignition source can cause a combustible dust explosion. Keep dust levels to a minimum and follow applicable regulations.

**Precautions for Safe Handling:** Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Avoid breathing dust. Handle empty containers with care because they may still present a hazard. Do not get in eyes, on skin, or on clothing.

**Hygiene Measures:** Handle in accordance with good industrial hygiene and safety procedures.

### 7.2. Conditions for Safe Storage, Including Any Incompatibilities

**Technical Measures:** Comply with applicable regulations.

**Storage Conditions:** Keep container closed when not in use. Store in a dry, cool place. Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials.

**Incompatible Materials:** Strong acids, strong bases, strong oxidizers.

### 7.3. Specific End Use(s)

Pharmaceutical.

## SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1. Control Parameters

For substances listed in Section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), AIHA (WEEL), NIOSH (REL), or OSHA (PEL).

Magnesium stearate (557-04-0)		
USA ACGIH	ACGIH TWA (mg/m <sup>3</sup> )	10 mg/m <sup>3</sup> (inhalable particulate matter) 3 mg/m <sup>3</sup> (respirable particulate matter)
Polyethylene glycol (25322-68-3)		
USA AIHA	WEEL TWA (mg/m <sup>3</sup> )	10 mg/m <sup>3</sup> (MW>200-aerosol)
Silica, amorphous (7631-86-9)		
USA NIOSH	NIOSH REL (TWA) (mg/m <sup>3</sup> )	6 mg/m <sup>3</sup>
USA IDLH	US IDLH (mg/m <sup>3</sup> )	3000 mg/m <sup>3</sup>
USA OSHA	OSHA PEL (TWA) (mg/m <sup>3</sup> )	6 mg/m <sup>3</sup>
USA OSHA	OSHA PEL (TWA) (ppm)	20 mppcf (80mg/m <sup>3</sup> /%SiO <sub>2</sub> )

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### 8.2. Exposure Controls

#### Appropriate Engineering Controls

: Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure. Ensure adequate ventilation, especially in confined areas. Ensure all national/local regulations are observed.

#### Personal Protective Equipment

: Gloves. Protective clothing. Protective goggles.



#### Materials for Protective Clothing

: Chemically resistant materials and fabrics.

#### Hand Protection

: Wear protective gloves.

#### Eye and Face Protection

: Chemical safety goggles.

#### Skin and Body Protection

: Wear suitable protective clothing.

#### Respiratory Protection

: If exposure limits are exceeded or irritation is experienced, approved respiratory protection should be worn. In case of inadequate ventilation, oxygen deficient atmosphere, or where exposure levels are not known wear approved respiratory protection.

#### Other Information

: When using, do not eat, drink or smoke.

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1. Information on Basic Physical and Chemical Properties

Physical State	: Solid
Appearance	: Tablet
Odor	: No data available
Odor Threshold	: No data available
pH	: No data available
Evaporation Rate	: No data available
Melting Point	: No data available
Freezing Point	: No data available
Boiling Point	: No data available
Flash Point	: No data available
Auto-ignition Temperature	: No data available
Decomposition Temperature	: No data available
Flammability (solid, gas)	: No data available
Vapor Pressure	: No data available
Relative Vapor Density at 20°C	: No data available
Relative Density	: No data available
Solubility	: No data available
Partition Coefficient: N-Octanol/Water	: No data available
Viscosity	: No data available

### 9.2. Other Information

No additional information available

## SECTION 10: STABILITY AND REACTIVITY

- 10.1. **Reactivity:** Hazardous reactions will not occur under normal conditions.
- 10.2. **Chemical Stability:** Stable under recommended handling and storage conditions (see Section 7).
- 10.3. **Possibility of Hazardous Reactions:** Hazardous polymerization will not occur.
- 10.4. **Conditions to Avoid:** Direct sunlight, extremely high or low temperatures, and incompatible materials.
- 10.5. **Incompatible Materials:** Strong acids, strong bases, strong oxidizers.
- 10.6. **Hazardous Decomposition Products:** None expected under normal conditions of use.

## SECTION 11: TOXICOLOGICAL INFORMATION

### 11.1. Information on Toxicological Effects

**Acute Toxicity:** Oral: Not classified.

(.+.)-2-(tert-Butylamino)-3'-chloropropiophenone hydrochloride (31677-93-7)	
LD50 Oral Rat	482 mg/kg

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<b>2-Pyrrolidinone, 1-ethenyl-, homopolymer (9003-39-8)</b>	
LD50 Oral Rat	100000 mg/kg
<b>Silica, amorphous, fumed, crystalline-free (112945-52-5)</b>	
LD50 Oral Rat	3160 mg/kg
<b>Magnesium stearate (557-04-0)</b>	
LD50 Oral Rat	> 2000 mg/kg
<b>Ethylcellulose (9004-57-3)</b>	
LD50 Oral Rat	> 5 g/kg
<b>Polyethylene glycol (25322-68-3)</b>	
LD50 Oral Rat	47000 mg/kg
LD50 Dermal Rabbit	> 20 g/kg
<b>Eudragit L30D 55#</b>	
ATE (Dust/Mist)	1.50 mg/l/4h
<b>Silica, amorphous (7631-86-9)</b>	
LD50 Oral Rat	7900 mg/kg
LD50 Dermal Rabbit	> 2000 mg/kg
<b>Triethyl citrate (77-93-0)</b>	
LD50 Oral Rat	5900 mg/kg
LD50 Dermal Rabbit	> 5 g/kg
LC50 Inhalation Rat	1300 ppm (Exposure time: 6 h)

**Skin Corrosion/Irritation:** Not classified

**Serious Eye Damage/Irritation:** Not classified

**Respiratory or Skin Sensitization:** Not classified

**Germ Cell Mutagenicity:** Not classified

**Carcinogenicity:** Not classified

<b>2-Pyrrolidinone, 1-ethenyl-, homopolymer (9003-39-8)</b>	
IARC group	3
<b>Silica, amorphous, fumed, crystalline-free (112945-52-5)</b>	
IARC group	3
<b>Silica, amorphous (7631-86-9)</b>	
IARC group	3

**Reproductive Toxicity:** Not classified

**Specific Target Organ Toxicity (Single Exposure):** Not classified

**Specific Target Organ Toxicity (Repeated Exposure):** Not classified

**Aspiration Hazard:** Not classified

**Symptoms/Injuries After Inhalation:** Prolonged exposure may cause irritation.

**Symptoms/Injuries After Skin Contact:** Prolonged exposure may cause skin irritation.

**Symptoms/Injuries After Eye Contact:** May cause slight irritation to eyes.

**Symptoms/Injuries After Ingestion:** This material is harmful orally and can cause adverse health effects or death in significant amounts.

**Chronic Symptoms:** None expected under normal conditions of use.

## SECTION 12: ECOLOGICAL INFORMATION

### 12.1. Toxicity

**Ecology - General** : Not classified.

<b>Silica, amorphous (7631-86-9)</b>	
LC50 Fish 1	5000 mg/l (Exposure time: 96 h - Species: Brachydanio rerio [static])
EC50 Daphnia 1	7600 mg/l (Exposure time: 48 h - Species: Ceriodaphnia dubia)

### 12.2. Persistence and Degradability

<b>Bupropion Hydrochloride Extended Release Tablets USP 150 mg &amp; 300 mg</b>	
Persistence and Degradability	Not established.

### 12.3. Bioaccumulative Potential

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Bioaccumulative Potential	Not established.
Silica, amorphous (7631-86-9)	
BCF Fish 1	(no bioaccumulation expected)

### 12.4. Mobility in Soil

No additional information available

### 12.5. Other Adverse Effects

Other Information : Avoid release to the environment.

## SECTION 13: DISPOSAL CONSIDERATIONS

### 13.1. Waste Treatment Methods

**Waste Disposal Recommendations:** Dispose of contents/container in accordance with local, regional, national, and international regulations.

**Additional Information:** Container may remain hazardous when empty. Continue to observe all precautions.

**Ecology - Waste Materials:** Avoid release to the environment.

## SECTION 14: TRANSPORT INFORMATION

The shipping description(s) stated herein were prepared in accordance with certain assumptions at the time the SDS was authored, and can vary based on a number of variables that may or may not have been known at the time the SDS was issued.

**14.1. In Accordance with DOT** Not regulated for transport

**14.2. In Accordance with IMDG** Not regulated for transport

**14.3. In Accordance with IATA** Not regulated for transport

## SECTION 15: REGULATORY INFORMATION

### 15.1. US Federal Regulations

<b>Bupropion Hydrochloride Extended Release Tablets USP 150 mg &amp; 300 mg</b>	
<b>SARA Section 311/312 Hazard Classes</b>	Physical hazard - Combustible dust Health hazard - Acute toxicity (any route of exposure)
<b>2-Pyrrolidinone, 1-ethenyl-, homopolymer (9003-39-8)</b>	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
<b>EPA TSCA Regulatory Flag</b>	XU - XU - indicates a substance exempt from reporting under Chemical Data Reporting Rule (formerly the Inventory Update Reporting Rule), i.e., Partial Updating of the TSCA Inventory Data Base Production and Site Reports (40 CFR 711).
<b>Magnesium stearate (557-04-0)</b>	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
<b>Ethylcellulose (9004-57-3)</b>	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
<b>EPA TSCA Regulatory Flag</b>	XU - XU - indicates a substance exempt from reporting under Chemical Data Reporting Rule (formerly the Inventory Update Reporting Rule), i.e., Partial Updating of the TSCA Inventory Data Base Production and Site Reports (40 CFR 711).
<b>Polyethylene glycol (25322-68-3)</b>	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
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<b>Silica, amorphous (7631-86-9)</b>	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
<b>Triethyl citrate (77-93-0)</b>	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
<b>15.2. US State Regulations</b>	
<b>Silica, amorphous (7631-86-9)</b>	
U.S. - Massachusetts - Right To Know List	
U.S. - Pennsylvania - RTK (Right to Know) List	

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## SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

**Date of Preparation or Latest Revision** : 06/21/2018

**Other Information** : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200

*This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.*

SDS US (GHS HazCom)