


## Safety Data Sheet

### Bupropion Hydrochloride Extend-Release Tablet, 150mg, 300mg

#### SECTION 1 IDENTIFICATION

<b>Product identifier</b>	Bupropion Hydrochloride Extend-Release Tablet, 150mg, 300mg
<b>Recommended use</b>	Oral
<b>Manufacturer</b>	
<b>Company name</b>	TWi Pharmaceuticals, Inc.
<b>Address</b>	3F, No 41, Lane 221, Kang Chien Rd, Taipei, Taiwan.
<b>Telephone</b>	886-2-26573350
<b>Fax</b>	886-2-26573391
<b>E-mail address</b>	QA.Service@twipharma.com
<b>Emergency phone number</b>	1-844-518-2989

#### SECTION 2 HAZARD IDENTIFICATION

<b>Physical hazards</b>	Not classified.	
<b>Health hazards</b>	Acute toxicity, oral	Category 4
	Serious eye damage/eye irritation	Category 2B
<b>Environmental hazards</b>	Hazardous to the aquatic environment, acute hazard Category 1	
	Hazardous to the aquatic environment, long-term hazard Category 1	
<b>Label elements</b>		
<b>Symbols</b>		
<b>Signal word</b>	Warning	
<b>Hazard statement</b>	Harmful if swallowed. Causes eye irritation. Very toxic to aquatic life. Very toxic to aquatic life with long lasting effects.	
<b>Precautionary statement</b>		
<b>Prevention</b>	Wash thoroughly after handling. Do not eat, drink or smoke when using this product. Avoid release to the environment	
<b>Response</b>	IF SWALLOWED: Call a POISON CENTRE or doctor/physician if you feel unwell. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Rinse mouth. If eye irritation persists: Get medical advice/attention. Collect spillage.	
<b>Storage</b>	Not available.	
<b>Disposal</b>	Dispose of contents/container in accordance with local/regional/national/international regulations.	

#### SECTION 3 COMPOSITION/INFORMATION ON INGREDIENTS

Ingredient	Exposure Limit	CAS#
Bupropion Hydrochloride	Not founded	31677-93-7

Non-hazardous excipients	Not founded	-
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## SECTION 4 FIRST-AID MEASURES

<b>Inhalation</b>	Move to fresh air. If breathing is difficult, trained personnel should give oxygen. Call a physician if symptoms develop or persist. Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
<b>Skin contact</b>	Immediately flush skin with plenty of water. Take off contaminated clothing and wash before reuse. Get medical attention if symptoms occur.
<b>Eye contact</b>	Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.
<b>Ingestion</b>	If swallowed, rinse mouth with water (only if the person is conscious). If ingestion of a large amount does occur, call a poison control center immediately. Do not induce vomiting without advice from poison control center.
<b>Potential delayed effects</b>	The following adverse effects have been noted with therapeutic use of this material: insomnia; agitation; anxiety; headache; tremor; visual disturbances; dry mouth; nausea; vomiting; rash; depression; constipation; convulsions.
<b>Personal protection for first-aid responders</b>	In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.
<b>Notes to physician</b>	No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information center.

## SECTION 5 FIRE-FIGHTING MEASURES

<b>Extinguishing Media</b>	Water. Foam. Dry chemical powder. Carbon dioxide (CO <sub>2</sub> ).
<b>Extinguishing media to avoid</b>	None known.
<b>HAZCHEM Code Number</b>	None.
<b>Specific hazards during fire fighting</b>	During fire, gases hazardous to health may be formed.
<b>Specific fire fighting procedures</b>	Move containers from fire area if you can do so without risk.
<b>Protection of fire-fighters</b>	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
<b>Hazards from combustion products</b>	None.
<b>Specific methods</b>	Use standard firefighting procedures and consider the hazards of other involved materials.
<b>General fire hazards</b>	No unusual fire or explosion hazards noted.

## SECTION 6 ACCIDENTAL RELEASE MEASURES

<b>Personal precautions, protective equipment and emergency procedures</b>	Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Wear appropriate protective equipment and clothing during clean-up. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Local authorities should be
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advised if significant spillages cannot be contained. For personal protection, see section 8.

**Spill cleanup methods**

Prevent entry into waterways, sewer, basements or confined areas.

Large Spills: Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible. Cover with plastic sheet to prevent spreading. Absorb in vermiculite, dry sand or earth and place into containers. Following product recovery, flush area with water.

Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.

Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS.

**Environmental precautions**

Avoid release to the environment. Inform appropriate managerial or supervisory personnel of all environmental releases. Prevent further leakage or spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground.

**SECTION 7 HANDLING AND STORAGE**

**Storage**

Store at 20° to 25°C (68° to 77°F).

Dispense in a tight container

**SECTION 8 EXPOSURE CONTROLS/PERSONAL PROTECTION**

**Respiratory Protection**

Protection from inhalation is not normally necessary. If ventilation is inadequate or dust is likely to generate, use of suitable dust mask would be appropriate.

**Skin Protection**

Skin protection is not normally necessary, however it is good practice to avoid contact with chemical to use suitable gloves when handling.

**Eye protection**

Eye protection is not normally necessary. If concerned wear protective goggles or glasses. Wash hands prior to touching eye and in particular handling contact lenses.

**Protective Clothing**

Protective clothing is not normally necessary, however it is good practice to use apron.

**SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES**

**Appearance**

<b>Physical state/ Form</b>	Solid white coated tablet
<b>Odour</b>	N/A
<b>Odour threshold</b>	N/A
<b>Melting point/freezing point</b>	N/A
<b>Initial boiling point and boiling range</b>	N/A
<b>Evaporation rate</b>	N/A
<b>Vapour density</b>	N/A
<b>Reactivity in water</b>	N/A
<b>Specific gravity</b>	N/A
<b>Solubility</b>	N/A

## SECTION 10 STABILITY AND REACTIVITY

Stable under recommended storage conditions.

## SECTION 11 TOXICOLOGICAL INFORMATION

### Information on the likely routes of exposure (short-term exposure)

<b>Inhalation</b>	Health injuries are not known or expected under normal use. Inhalation of dusts may cause respiratory irritation.
<b>Skin contact</b>	Health injuries are not known or expected under normal use. Dust or powder may irritate the skin.
<b>Eye contact</b>	Health injuries are not known or expected under normal use. Dust or powder may irritate eye tissue.
<b>Ingestion</b>	Health injuries are not known or expected under normal use. May be harmful if swallowed

### Toxicology (long-term exposure)

<b>Carcinogenicity</b>	Not classifiable as to carcinogenicity to humans. Carcinogenic effects are not expected as a result of occupational exposure.
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## SECTION 12 ECOLOGICAL INFORMATION

Do not allow product to enter drinking water supplies, waste water or soil

## SECTION 13 DISPOSAL CONSIDERATIONS

<b>Disposal instructions</b>	Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Do not discharge into drains, water courses or onto the ground. Dispose in accordance with all applicable regulations.
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## SECTION 14 TRANSPORT INFORMATION

The product is not hazards when shipped via air (IATA), ground (DOT), or sea (IMDG).

## SECTION 15 REGULATORY INFORMATION

Generic Medicine. Approved by USFDA & the ANDA Number is A210081

## SECTION 16 OTHER INFORMATION

No information found.

<b>Issue date</b>	August 27, 2018
<b>Version #</b>	01
<b>Disclaimer</b>	TWi Pharmaceutical, Inc. cannot anticipate all conditions under which this information and its product, or the products of other manufacturers in combination with its product, may be used. It is the user's responsibility to

ensure safe conditions for handling, storage and disposal of the product, and to assume liability for loss, injury, damage or expense due to improper use. The information in the sheet was written based on the best knowledge and experience currently available.