

**SAFETY DATA SHEET**

 -----  
 Date: 04/14/2020

Generic Name: Bupropion Hydrochloride Extended-Release Tablets, USP (XL)

 Brand Equivalent: WELLBUTRIN  
 -----

<b>SECTION 1: IDENTIFICATION</b>	
<b>Product Name</b>	Bupropion Hydrochloride Extended-Release Tablets, USP (XL), 150 mg & 300 mg
<b>Active substance</b>	Bupropion Hydrochloride
<b>Synonyms</b>	N/A
<b>Formula</b>	C <sub>13</sub> H <sub>18</sub> ClNO·HCl
<b>Intended Use</b>	Treatment of major depressive disorder (MDD)
<b>Chemical Name</b>	1-Propanone, 1-(3-chlorophenyl)-2-[(1, 1-dimethylethyl) amino]-, hydrochloride, (±)-  (or)  (±)-2-( <i>tert</i> -Butylamino)-3'-chloropropiophenone hydrochloride
<b>Manufacturer Name &amp; Address</b>	ScieGen Pharmaceuticals, Inc. 89 Arkay drive, Hauppauge, NY 11788.
<b>Telephone No.</b>	631-524-5509, 631-434-2723

## 2. HAZARDS IDENTIFICATION:

### Classified hazards

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

### Label elements

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

### Hazard(s) not otherwise classified (HNOC)

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

3. Composition/Information on ingredients		
Components	CAS-No	%
Bupropion Hydrochloride	31677-93-7	150 mg or 300 mg per tablet
Copovidone	25086-89-9	Proprietary
Microcrystalline Cellulose	9004-34-6	Proprietary
Hydrochloric Acid	7647-01-0	Proprietary
Hydroxypropyl Methyl Cellulose	9004-65-3	Proprietary
Magnesium Stearate	557-04-0	Proprietary
Colloidal Silicon Dioxide,	7631-86-9	Proprietary
Talc	14807-96-6	Proprietary
Methacrylic Acid Copolymer Dispersion,	25212-88-8	Proprietary
Triethyl Citrate, NF	77-93-0	Proprietary
Film Coating	Not assigned	Proprietary

4. FIRST AID MEASURES	
<b>Eye contact</b>	Immediately flush eyes with plenty of water for at least 15 minutes.
<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>Inhalation</b>	In case of accident by inhalation: remove casualty to fresh air and keep at rest. If breathing is difficult, trained personnel should give oxygen. If not breathing, give artificial respiration. Get medical attention if symptoms occur.
<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.
<b>Most important symptoms/effects, acute and delayed</b>	Irritation of eyes and mucous membranes. 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>Indication of immediate medical attention and special treatment needed</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 centre.
<b>General information</b>	Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Pre-placement and periodic health surveillance is not usually indicated. The final determination of the need for health surveillance should be determined by local risk assessment.

<b>5. FIRE-FIGHTING MEASURES</b>	
<b>Suitable extinguishing media</b>	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO <sub>2</sub> ).
<b>Unsuitable extinguishing media</b>	None known.
<b>Specific hazards arising from the chemical</b>	During fire, gases hazardous to health may be formed.
<b>Special protective equipment and precautions for firefighters</b>	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
<b>Fire-fighting equipment/instructions</b>	In the event of fire, cool tanks with water spray.
<b>Specific methods</b>	Cool containers exposed to flames with water until well after the fire is out.

<b>6. ACCIDENTAL RELEASE MEASURES</b>	
<b>Personal precautions, protective equipment and emergency procedures</b>	Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Keep out of low areas. Wear appropriate personal protective equipment. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the MSDS.
<b>Methods and materials for containment and cleaning up</b>	Stop the flow of material, if this is without risk. Collect spillage. Prevent entry into waterways, sewer, basements or confined areas. Following product recovery, flush area with water. For waste disposal, see section 13 of the MSDS.

<b>Environmental precautions</b>	Avoid release to the environment. Contact local authorities in case of spillage to drain/aquatic environment. Prevent further leakage or spillage if safe to do so. Do not contaminate water. Avoid discharge into drains, water courses or onto the ground.
----------------------------------	--

<b>7. HANDLING AND STORAGE</b>	
<b>Precautions for safe handling</b>	Do not taste or swallow. Avoid contact with eyes. Avoid prolonged exposure. Provide adequate ventilation. Wear appropriate personal protective equipment. Observe good industrial hygiene practices. When using, do not eat, drink or smoke. Wash hands thoroughly after handling. Avoid release to the environment. Do not empty into drains.
<b>Conditions for safe storage, including any incompatibilities</b>	Store in original tightly closed container. Store in a cool, dry place out of direct sunlight. Store away from incompatible materials (see Section 10 of the MSDS).

<b>8. Exposure controls/Personal protection</b>	
<b>Biological limit values</b>	No biological exposure limits noted for the ingredient(s).
<b>Appropriate engineering controls</b>	Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.
<b>Individual protection measures, such as personal protective equipment</b>	
<b>Eye/face protection</b>	If contact is likely, safety glasses with side shields are recommended.
<b>Hand protection</b>	The choice of an appropriate glove does not only depend on its material but also on other quality features and is different from one producer to the other. Glove selection must take into account any solvents and other hazards present.
<b>Other</b>	Not normally needed.
<b>Respiratory protection</b>	No personal respiratory protective equipment normally required.
<b>Thermal hazards</b>	Wear appropriate thermal protective clothing, when necessary.
<b>General hygiene considerations</b>	An occupational/industrial hygiene monitoring method has been developed for this material. For advice on suitable monitoring methods, seek guidance

	from a qualified environment, health and safety professional. Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants. When using, do not eat, drink or smoke.
--	---

9. PHYSICAL AND CHEMICAL PROPERTIES	
<b>General Information</b>	
<i>Appearance</i> <b>Physical State</b> <b>Form</b> <b>Color</b>	Solid Tablet White to Pale Yellow
<i>Odor</i> <b>Odor Threshold</b>	Not available
<b>pH</b>	Not available
<b>Melting point/freezing point</b>	Not available
<b>Initial boiling point and boiling range</b>	Not available
<b>Flash point</b>	Not available
<b>Evaporation rate</b>	Not available
<b>Flammability (solid, gas)</b>	Not available
<b>Upper/lower flammability or explosive limits</b> Flammability limit – lower (%) Flammability limit – upper (%) Explosive limit - lower (%) Explosive limit - upper (%)	Not available Not available Not available Not available
<b>Vapor pressure</b>	Not available
<b>Vapor density</b>	Not available
<b>Relative density</b>	Not available
<b>Solubility (ies)</b>	Not available
<b>Partition coefficient (n-octanol/water)</b>	Not available
<b>Auto-ignition temperature</b>	Not available
<b>Decomposition temperature</b>	Not available
<b>Viscosity</b>	Not available

10. Stability and Reactivity	
<b>Reactivity</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.

<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>	Contact with incompatible materials.
<b>Incompatible materials</b>	Strong oxidizing agents. Fluorine.
<b>Hazardous decomposition products</b>	Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.

<b>11. Toxicological Information</b>		
<b>Information on likely routes of exposure</b>		
<b>Ingestion</b>	Health injuries are not known or expected under normal use. May be harmful if swallowed.	
<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>Symptoms related to the physical, chemical and toxicological characteristics</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. No specific target organ effects have been identified.	
<b>Information on toxicological effects</b>		
<b>Acute toxicity</b>	Health injuries are not known or expected under normal use. Adverse effects might occur with repeated ingestion.	
<b>Components</b>	<b>Species</b>	<b>Test Results</b>
BUPROPION HYDROCHLORIDE (CAS 31677-93-7)		
<b>Acute</b> <i>Oral</i> <i>LD50</i>	Mouse Rat	544 - 636 mg/kg 482 - 607 mg/kg
<b>Chronic</b> <i>Oral</i> <i>LOEL</i>	Dog Rat	40 mg/kg/day, 52 weeks 100 mg/kg/day, 104 weeks 25 mg/kg/day, 55 weeks
<i>NOAEL</i>	Dog Rat	40 mg/kg/day, 52 weeks 100, 104 weeks

<b>Subacute</b> <i>Oral</i> NOAEL	Dog	100 mg/kg/day, 55 weeks
<b>Subchronic</b> <i>Oral</i> NOAEL	Rat	150 mg/kg/day, 47 Day
COPOVIDONE (CAS 25086-89-9) <b>Acute</b> <i>Oral</i>	Rat	450 mg/kg/day, 90 Day
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)  <b>Acute</b> <i>Dermal</i> LD50	Rabbit	>5,000 mg/kg
<i>Oral</i> LD50	Rat	> 2000 mg/kg
CYSTEINE HYDROCHLORIDE (CAS 52-89-1)  <b>Acute</b> <i>Oral</i> LD50		No data available
HYDROXYPROPYL METHYL CELLULOSE (CAS 9004-65-3)  <b>Acute</b> <i>Oral</i> LD50	Rat	> 2000 mg/kg
MAGNESIUM STEARATE (CAS 557-04-0)  <b>Acute</b> <i>Oral</i> LD50	Rat	> 2000 mg/kg
Artificial black berry flavor <b>Acute</b> <i>Oral</i>	-	As per the supplier GRAS statement, Maximum Usage Limit is 2.5%



LD50		
------	--	--

12. Ecological Information	
<b>Ecotoxicity</b>	No data available
<b>Persistence and degradability</b>	No data available
<b>Bioaccumulative potential</b>	No data available
<b>Mobility in soil</b>	No data available
<b>Other adverse effects</b>	No data available

13. Disposal considerations	
<b>Disposal instructions</b>	Collect and reclaim or dispose in sealed containers at licensed waste disposal site. This material and its container must be disposed of as hazardous waste. Do not allow this material to drain into sewers/water supplies. Do not contaminate ponds, waterways or ditches with chemical or used container. Dispose of contents/container in accordance with local/regional/ national/ international regulations.
<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>	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).
<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	
<b>DOT</b>	
UN number	UN3077
UN proper shipping name	Environmentally hazardous substances, solid, n.o.s. (BUPROPION HYDROCHLORIDE, FORMULATED PRODUCT), MARINE POLLUTANT
Transport hazard class(es)	9
Subsidiary class(es)	Not available
Packing group	III



Special precautions for user	Not available
<b>IMDG</b>	
UN/ID No.	1230
Proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (BUPROPION HYDROCHLORIDE, FORMULATED PRODUCT)
Transport hazard class(es)	9
Subsidiary class(es)	-
Packing group	III
Special precautions for user	Not available

<b>15. Regulatory Information</b>	
<b>US federal regulations</b>	
TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)	Not regulated.
CERCLA Hazardous Substance List (40 CFR 302.4)	Not listed.
US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)	Not listed.
SARA 304 Emergency release notification	Not regulated.
<b>Other federal regulations</b>	
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.
Food and Drug Administration (FDA)	Not regulated.
<b>US state regulations</b>	
<b>US. California Proposition 65</b>	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.

<b>16. Other information</b>	
<b>Recommended Restrictions for Use:</b>	Not available.
<b>Prepared on</b>	04/14/2020
<b>Revision</b>	00
	The information and recommendations in this safety data sheet are, to the



**SciGen Pharmaceuticals, Inc.**  
89 Arkay drive  
Hauppauge, New York 11788  
Tel: 631-524-5509, 631-434-2723  
Fax: 631-357-3178

**Disclaimer**

best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.