

SAFETY DATA SHEET

 Date: 05/18/2018

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

 Brand Equivalent: WELLBUTRIN

SECTION 1: IDENTIFICATION	
Product Name	Bupropion Hydrochloride Extended-Release Tablets, USP (SR), 100 mg, 150 mg and 200 mg
Active substance	Bupropion Hydrochloride
Synonyms	N/A
Formula	C ₁₃ H ₁₈ ClNO·HCl
Intended Use	Treatment of major depressive disorder (MDD)
Chemical Name	1-Propanone, 1-(3-chlorophenyl)-2-[(1, 1-dimethylethyl) amino]-, hydrochloride, (±)- (or) (±)-2-(<i>tert</i> -Butylamino)-3'-chloropropiophenone hydrochloride
Manufacturer Name & Address	ScieGen Pharmaceuticals, Inc. 89 Arkay drive, Hauppauge, NY 11788.
Telephone No.	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	100mg, 150 mg or 200 mg per tablet
Copovidone	25086-89-9	Proprietary
Microcrystalline Cellulose	9004-34-6	Proprietary
Cysteine Hydrochloride	52-89-1	Proprietary
Hydroxypropyl Methyl Cellulose	9004-65-3	Proprietary
Magnesium Stearate	557-04-0	Proprietary
Artificial black berry flavor	-	Proprietary
Film Coating	Not assigned	Proprietary

4. FIRST AID MEASURES	
Eye contact	Immediately flush eyes with plenty of water for at least 15 minutes.
Skin contact	Immediately flush skin with plenty of water. Take off contaminated clothing and wash before reuse. Get medical attention if symptoms occur.
Inhalation	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.
Ingestion	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.
Most important symptoms/effects, acute and delayed	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.
Indication of immediate medical attention and special treatment needed	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.

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

6. ACCIDENTAL RELEASE MEASURES	
Personal precautions, protective equipment and emergency procedures	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.
Methods and materials for containment and cleaning up	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.
Environmental precautions	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.

7. HANDLING AND STORAGE	
Precautions for safe handling	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.
Conditions for safe storage, including any incompatibilities	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).

8. Exposure controls/Personal protection	
Biological limit values	No biological exposure limits noted for the ingredient(s).
Appropriate engineering controls	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.
Individual protection measures, such as personal protective equipment	
Eye/face protection	If contact is likely, safety glasses with side shields are recommended.
Hand protection	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.
Other	Not normally needed.
Respiratory protection	No personal respiratory protective equipment normally required.
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
General hygiene considerations	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	
General Information	
<i>Appearance</i> Physical State Form Color	Solid Tablet 100 mg tablets: blue 150 mg tablets: purple 200 mg tablets: pink
<i>Odor</i> Odor Threshold	Black berry flavor odor Not available
pH	Not available
Melting point/freezing point	Not available
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 (%) Flammability limit – upper (%) Explosive limit - lower (%) Explosive limit - upper (%)	Not available Not available Not available Not available
Vapor pressure	Not available
Vapor density	Not available
Relative density	Not available
Solubility (ies)	Not available
Partition coefficient (n-octanol/water)	Not available
Auto-ignition temperature	Not available
Decomposition temperature	Not available
Viscosity	Not available

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. Fluorine.

Hazardous decomposition products	Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.
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11. Toxicological Information		
Information on likely routes of exposure		
Ingestion	Health injuries are not known or expected under normal use. May be harmful if swallowed.	
Inhalation	Health injuries are not known or expected under normal use. Inhalation of dusts may cause respiratory irritation.	
Skin contact	Health injuries are not known or expected under normal use. Dust or powder may irritate the skin.	
Eye contact	Health injuries are not known or expected under normal use. Dust or powder may irritate eye tissue.	
Symptoms related to the physical, chemical and toxicological characteristics	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.	
Information on toxicological effects		
Acute toxicity	Health injuries are not known or expected under normal use. Adverse effects might occur with repeated ingestion.	
Components	Species	Test Results
BUPROPION HYDROCHLORIDE (CAS 31677-93-7)		
Acute <i>Oral</i> <i>LD50</i>	Mouse Rat	544 - 636 mg/kg 482 - 607 mg/kg
Chronic <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 100 mg/kg/day, 55 weeks
Subacute <i>Oral</i> <i>NOAEL</i>	Dog	150 mg/kg/day, 47 Day

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

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

13. Disposal considerations	
Disposal instructions	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.
Local disposal regulations	Dispose in accordance with all applicable regulations.
Hazardous waste code	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
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 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
IMDG	
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

15. Regulatory Information	
US federal regulations	
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.
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.
Food and Drug Administration (FDA)	Not regulated.
US state regulations	
US. California Proposition 65	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.

16. Other information	
Recommended Restrictions for Use:	Not available.
Prepared on	05/18/2018
Revision	01
Disclaimer	The information and recommendations in this safety data sheet are, to the 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.