

SAFETY DATA SHEET

Section 1: Identification	
Material	Bupropion Hydrochloride Extended-Release Tablets, USP (SR), 100 mg, 150 mg and 200 mg
Recommended use	Treatment of major depressive disorder (MDD)
Manufacturer	Annora Pharma Private Limited, Survey No. 261, Annaram Village, Gummadidala Mandal, Sanga Reddy, Telangana 502313, India (IND)
Distributor	Camber Pharmaceuticals, Inc., Piscataway, NJ 08854
Section 2: Hazard(s) Identification	
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.	
Section 3: Composition/Information on Ingredients	
Ingredients	CAS
Bupropion Hydrochloride	31677-93-7
Colloidal Silicon Dioxide	7631-86-9
Diluted Hydrochloric acid	7647-01-0
Hypromellose	9004-65-3
Magnesium Stearate	557-04-0
Microcrystalline Cellulose	9004-34-6
Opacode Black	NA
Opadry	NA
Sodium Stearyl Fumarate	4070-80-8

Section 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 and effects	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.
Section 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.

Section 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.
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.
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.
Section 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 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.
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.
Section 9: Physical and Chemical Properties	
Physical State	Solid
Description	<p>Bupropion hydrochloride extended-release tablets USP (SR), 100 mg of bupropion hydrochloride are red colored, round biconvex bevel edged film coated tablets imprinted with 'V1 48' on one side and plain on other side are supplied as follows:</p> <p style="padding-left: 40px;">Bottle of 60 tablets NDC 31722-066-60 Bottle of 100 tablets NDC 31722-066-01 Bottle of 500 tablets NDC 31722-066-05</p> <p>Bupropion hydrochloride extended-release tablets USP (SR), 150 mg of bupropion hydrochloride are green colored, round biconvex bevel edged film coated tablets imprinted with 'V1 49' on one side and plain on other side are supplied as follows:</p> <p style="padding-left: 40px;">Bottle of 60 tablets NDC 31722-067-60 Bottle of 100 tablets NDC 31722-067-01 Bottle of 500 tablets NDC 31722-067-05</p>

Description	<p>Bupropion hydrochloride extended-release tablets USP (SR), 200 mg of bupropion hydrochloride are yellow colored, round biconvex bevel edged film coated tablets imprinted with 'V1 50' on one side and plain on other side are supplied as follows:</p> <p style="padding-left: 40px;">Bottle of 60 tablets NDC 31722-068-60 Bottle of 100 tablets NDC 31722-068-01 Bottle of 500 tablets NDC 31722-068-05</p> <p>Store at room temperature, 20° to 25°C (68° to 77°F); excursions permitted between 15°C and 30°C (59°F and 86°F) [see USP Controlled Room Temperature]. Protect from light and moisture.</p>
Section 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.
Section 11: Toxicological Information	
Inhalation	No data available
Skin contact	No data available
Eye contact	No data available
Section 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

Section 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
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.
Section 14: Transport Information	
DOT	Non-hazardous material
Special precautions for user	Not available
Section 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	Not listed.
SARA 304 Emergency release notification	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.

Section 16: Other Information, including date of preparation or last revision

Issue Date: 15-11-2023

Version: 01

Further information

Revision date: 15-11-2023

Revision note: NDC numbers for 100 ct for 100 mg 150 mg, & 200 mg updated.

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.

Annora Pharma Private Limited shall not be held liable for any damage resulting from handling or from contact with the above product. Annora Pharma Private Limited reserves the right to revise this SDS.