Safety Data Sheet

Section 1: Identification

Product identifier

Product Name
- **Wellbutrin® XL (bupropion hydrochloride extended release tablets) 150-300 mg**

Product Code
- NDC 0187-0730-30; NDC 0187-0730-90; NDC 0187-0731-30

Relevant identified uses of the substance or mixture and uses advised against

Recommended use
- WELLBUTRIN XL® (bupropion hydrochloride extended-release tablets) is indicated for the treatment of major depressive disorder (MDD) and for the prevention of seasonal major depressive episodes in patients with a diagnosis of seasonal affective disorder (SAD).

Restrictions on use
- Refer to the product insert and/or prescribing information for restrictions on use and contraindications.

Details of the supplier of the safety data sheet

Manufacturer
- Valeant Pharmaceuticals International, Inc.

100 LifeSciences Parkway
Steinbach R5G 1Z7
Canada
valeant.com

Telephone (General)
- 1-800-321-4576

Emergency telephone number

Manufacturer
- 1-800-535-5053 - US - Infotrac

Manufacturer
- +1 352-323-3500 - International - Infotrac

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to consumer use of the product.

Section 2: Hazard Identification

UN GHS

According to: UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

Classification of the substance or mixture

UN GHS
- Acute Toxicity Oral 4
  Carcinogenicity 2
  Reproductive Toxicity 2
  Specific Target Organ Toxicity Repeated Exposure 1

Label elements

UN GHS

DANGER

Precautionary statements

Prevention
- Do not handle until all safety precautions have been read and understood.
  Do not breathe dust, fume, gas, mist, vapours and/or spray.
  Use personal protective equipment as required.
  Wash thoroughly after handling.

Response
- Get medical advice/attention if you feel unwell.
  IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician if you feel unwell.
  IF exposed or concerned: Get medical advice/attention.

Storage/Disposal
- Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

Other hazards

UN GHS
- No data available

Section 3 - Composition/Information on Ingredients

Substances

- Material does not meet the criteria of a substance according to United Nations Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

Mixtures

Composition			
Chemical Name	**Identifiers**	**%**	**Classifications According to Regulation/Directive**
Bupropion hydrobromide	**CAS:**905818-69-1	78.53% TO 83.46%	**UN GHS:** NDA
Colloidal silicon dioxide	**CAS:**7631-86-9 **EINECS:**231-545-4	N/A	**UN GHS:** NDA
Ethylcellulose	**CAS:**9004-57-3	N/A	**UN GHS:** NDA
Eudragit L30 D	**CAS:**25212-88-8	N/A	**UN GHS:** NDA
Glyceryl behenate	**CAS:**77538-19-3 **EINECS:**278-717-5	N/A	**UN GHS:** NDA
Opacode black S-1-17823	NDA	N/A	**UN GHS:** NDA
Polyethylene glycol 1450	**CAS:**25322-68-3	N/A	**UN GHS:** Skin Irrit. 3; Eye Irrit. 2B; Acute Tox. Oral 4
Polyvinyl alcohol	**CAS:**9002-89-5	N/A	**UN GHS:** Skin Irrit. 2; Eye Irrit. 2A
Povidone K90	**CAS:**9003-39-8	N/A	**UN GHS:** NDA
Triethyl citrate	**CAS:**77-93-0 **EINECS:**201-070-7	N/A	**UN GHS:** NDA

N/A - Designates that the chemical percentage of composition is not available as it is considered a trade secret.

Section 4: First-Aid Measures

Description of first aid measures

Inhalation
- Normal use of this product does not pose an inhalation hazard. However, during bulk handling should respiratory tract irritation develop, discontinue use and remove to fresh air. Get medical attention if irritation or other symptoms develop or persist.

Skin
- No specific treatment is necessary since this material is not likely to be hazardous by contact with the skin or mucous membranes. Immediately flush skin with large amounts of water. Remove contaminated clothing. Ifirritation (redness, rash, blistering)

develops, get medical attention.

Eye
- IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention immediately if symptoms occur.

Ingestion
- If swallowed, do not induce vomiting: seek medical advice immediately and show thiscontainer or label.

Most important symptoms and effects, both acute and delayed

- Overdoses of up to 30 g or more of bupropion have been reported. Seizure was reported in approximately one third of all cases. Other serious reactions reported with overdoses of bupropion alone included hallucinations, loss of consciousness, sinus tachycardia, and ECG changes such as conduction disturbances or arrhythmias. Fever, muscle rigidity, rhabdomyolysis, hypotension, stupor, coma, and respiratory failure have been reported mainly when bupropion was part of multiple drug overdoses.

Indication of any immediate medical attention and special treatment needed

Notes to Physician
- Treat according to accepted protocols. For additional guidance, refer to the current prescribing information.

Antidotes
- Overdose management: Ensure an adequate airway, oxygenation, and ventilation. Monitor cardiac rhythm and vital signs. EEG monitoring is also recommended for the first 48 hours post-ingestion. General supportive and symptomatic measures are also recommended. Induction of emesis is not recommended. Gastric lavage with a large-bore orogastric tube with appropriate airway protection, if needed, may be indicated if performed soon after ingestion or in symptomatic patients.Activated charcoal should be administered. There is no experience with the use of forced diuresis, dialysis, hemoperfusion, or exchange transfusion in the management of bupropion overdoses. No specific antidotes for bupropion are known.

Section 5: Fire-Fighting Measures

Extinguishing media

Suitable Extinguishing Media
- Water spray, carbon dioxide, dry chemical powder or appropriate foam for surrounding fire.

Unsuitable Extinguishing Media
- No data available

Special hazards arising from the substance or mixture

Unusual Fire and Explosion Hazards
- No data available

Hazardous Combustion Products
- No data available.

Advice for firefighters

- As in any fire, wear self-contained breathing apparatus and full protective gear to prevent contact with skin and eyes.

Section 6 - Accidental Release Measures

Personal precautions, protective equipment and emergency procedures

Personal Precautions
- No special controls or personal protection required under conditions of intended use. In the event of bulk spills, wear suitable protective eyewear, clothing, protective boots and protective gloves. Evacuate immediate area. Ensure adequate ventilation. Refer to Section 8.

Emergency Procedures
- Keep unauthorized personnel away. Clean up spilled tablets and place in sealed container. Avoid breaking tablets or creating dust during clean up.

Environmental precautions

- No data available on the environmental impact of this product.

Methods and material for containment and cleaning up

Containment/Clean-up Measures
- LARGE SPILLS: Use HEPA vacuum to clean up spill. If HEPA vacuum is not available, dampen spilled tablets with water prior to cleaning up to prevent dust cloud.

Section 7 - Handling and Storage

Precautions for safe handling

Handling
- Avoid breaking or crushing tablets. Minimize dust generation and accumulation. Use good safety and industrial hygiene practices.

Conditions for safe storage, including any incompatibilities

Storage
- Keep tightly closed. Store at controlled room temperature 25ºC/77ºF (excursions permitted to 15-30ºC/59-86ºF), to maintain product integrity. Use before date marked on carton and/or container. Protect from light.

Section 8 - Exposure Controls/Personal Protection

Control parameters

Exposure Limits/Guidelines
- Refer to the occupational exposure limits / guidelines for the individual product components.

Exposure Limits/Guidelines

	Result	NIOSH	Other Agency Information
Colloidal silicon dioxide (7631-86-9)	TWAs	6 mg/m3 TWA	Not established
Polyethylene glycol 1450 (25322-68-3)	TWAs	Not established	10 mg/m3 TWA (MW>200, aerosol)

Exposure controls

Engineering Measures/Controls
- NO SPECIAL CONTROLS ARE REQUIRED UNDER CONDITIONS OF INTENDED USE. Local exhaust ventilation should be provided when handling bulk product.

Personal Protective Equipment

Respiratory
- For bulk handling, the personal breathing protection should be determined based upon a risk assessment and in accordance with local regulations. Follow the OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or symptoms are experienced.

Eye/Face
- Wear protective eyewear (goggles, face shield, or safety glasses) when handling bulk product before closed in final packaging.

Hands
- Wear protective gloves when handling bulk product before closed in final packaging.

Skin/Body
- Avoid contact with skin.

General Industrial Hygiene Considerations
- Handle in accordance with good industrial hygiene and safety practice. Wash thoroughly with soap and water after handling.

Environmental Exposure Controls
- No data available

Section 9 - Physical and Chemical Properties

Information on Physical and Chemical Properties

Material Description			
Physical Form	Solid	Appearance/Description	Round tablets.
Color	Creamy white to pale yellow.	Odor	Not relevant
Odor Threshold	Not relevant		
General Properties			
Boiling Point	Not relevant	Melting Point/Freezing Point	239 to 241 °C(462.2 to 465.8 °F)
Decomposition Temperature	Not relevant	pH	No data available
Specific Gravity/Relative Density	Not relevant	Water Solubility	Soluble 312 mg/mL @ 20 °C(68 °F)
Solvent Solubility	Very soluble in methanol; Soluble in ethanol; Slightly soluble in acetone	Viscosity	Not relevant
Volatility			
Vapor Pressure	Not relevant	Vapor Density	Not relevant
Evaporation Rate	Not relevant		
Flammability			
Flash Point	Not relevant	UEL	Not relevant
LEL	Not relevant	Autoignition	Not relevant
Flammability (solid, gas)	Not relevant		
Environmental			
Octanol/Water Partition coefficient	No data available		

Section 10: Stability and Reactivity

Reactivity

- Stable under normal temperatures and pressures.

Chemical stability

- Hazardous polymerization will not occur.

Possibility of hazardous reactions

- No data available

Conditions to avoid

- Light, heat and humidity.

Incompatible materials

- Strong oxidizing agents.

Hazardous decomposition products

- When heated to decomposition, toxic fumes of nitrous oxides, sulfur oxides, hydrogen chloride and carbon oxides may be emitted.

Section 11 - Toxicological Information

Information on toxicological effects

GHS Properties	Classification
Acute toxicity	**UN GHS** • Acute Toxicity - Oral 4
Skin corrosion/Irritation	**UN GHS** • Classification criteria not met
Serious eye damage/Irritation	**UN GHS** • Classification criteria not met
Skin sensitization	**UN GHS** • Classification criteria not met

Respiratory sensitization	**UN GHS** • Classification criteria not met
Aspiration Hazard	**UN GHS** • Classification criteria not met
Carcinogenicity	**UN GHS** • Carcinogenicity 2
Germ Cell Mutagenicity	**UN GHS** • Classification criteria not met
Toxicity for Reproduction	**UN GHS** • Toxic to Reproduction 2
STOT-SE	**UN GHS** • Classification criteria not met
STOT-RE	**UN GHS** • Specific Target Organ Toxicity Repeated Exposure 1

Target Organs
- Central Nervous Sytem

Potential Health Effects

Inhalation

Acute (Immediate)
- Under normal conditions of use, no health effects are expected. Exposure to dust from broken tablets may cause irritation.

Chronic (Delayed)
- Repeated and prolonged exposure may cause irritation.

Skin

Acute (Immediate)
- Under normal conditions of use, no health effects are expected.

Chronic (Delayed)
- Repeated and prolonged exposure may cause irritation.

Eye

Acute (Immediate)
- May cause mild eye irritation with direct contact to eye.

Chronic (Delayed)
- Under normal conditions of use, no health effects are expected.

Ingestion

Acute (Immediate)
- May affect the heart and/or cardiovascular system. Symptoms may include hypotension, brdaycardia, heart block and cardiac failure. Toxic if ingested in excess of prescription dose.

Chronic (Delayed)
- No data available

Carcinogenic Effects			
	CAS	**IARC**	**NTP**
Colloidal silicon dioxide	7631-86-9	Group 3-Not Classifiable	Not Listed
Polyvinyl alcohol	9002-89-5	Group 3-Not Classifiable	Evidence of Carcinogenicity
Povidone K90	9003-39-8	Group 3-Not Classifiable	Not Listed

Reproductive Effects
- Pregnancy category C. Reproduction studies have been conducted in mice, rats, and rabbits. Administration of doses ranging from five to ten times (on a mg/kg basis) the daily recommended therapeutic dose has resulted in embryo and fetal lethality. These doses, in some studies, have been reported to cause skeletal abnormalities. In the perinatal/postnatal studies, there was an increased incidence of stillbirths at doses of 20 times the human dose or greater. Diltiazem is excreted in human milk. One report suggests that concentrations in breast milk may approximate serum levels.

Section 12 - Ecological Information

Toxicity

- This material has not been tested for environmental effects.

Persistence and degradability

- No data available

Bioaccumulative potential

- No data available

Mobility in Soil

- No data available

Other adverse effects

Section 13 - Disposal Considerations

Waste treatment methods

Product waste
- Waste characterizations and compliance with applicable laws are the responsibility solely of the waste generator.

Packaging waste
- Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

Section 14 - Transport Information

	UN number	UN proper shipping name	Transport hazard class (es)	Packing group	Environmental hazards
DOT	Not Applicable	Not Regulated	Not Applicable	Not Applicable	
TDG	Not Applicable	Not Regulated	Not Applicable	Not Applicable	
IMO/IMDG	Not Applicable	Not Regulated	Not Applicable	Not Applicable	
IATA/ICAO	Not Applicable	Not Regulated	Not Applicable	Not Applicable	

Special precautions for user
- No data available

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
- No data available

Section 15 - Regulatory Information

Safety, health and environmental regulations/legislation specific for the substance or mixture

SARA Hazard Classifications
- No data available

Inventory				
Component	**CAS**	**Canada DSL**	**EU EINECS**	**TSCA**
Bupropion hydrobromide	905818-69-1	No	No	No
Ethylcellulose	9004-57-3	Yes	No	Yes
Triethyl citrate	77-93-0	Yes	Yes	Yes
Colloidal silicon dioxide	7631-86-9	Yes	Yes	Yes
Glyceryl behenate	77538-19-3	No	Yes	No
Eudragit L30 D	25212-88-8	Yes	No	Yes
Povidone K90	9003-39-8	Yes	No	Yes
Polyvinyl alcohol	9002-89-5	Yes	No	Yes
Polyethylene glycol 1450	25322-68-3	Yes	No	Yes

Canada

Labor

Canada - WHMIS - Classifications of Substances

• Polyvinyl alcohol	9002-89-5	Not Listed
• Ethylcellulose	9004-57-3	Uncontrolled product according to WHMIS classification criteria
• Eudragit L30 D	25212-88-8	Not Listed
• Polyethylene glycol 1450	25322-68-3	Not Listed
• Triethyl citrate	77-93-0	Not Listed
• Povidone K90	9003-39-8	Uncontrolled product according to WHMIS classification criteria (listed under Providone)
• Colloidal silicon dioxide	7631-86-9	Uncontrolled product according to WHMIS classification criteria
• Glyceryl behenate	77538-19-3	Not Listed
• Bupropion hydrobromide	905818-69-1	Not Listed

Canada - WHMIS - Ingredient Disclosure List

• Polyvinyl alcohol	9002-89-5	Not Listed
• Ethylcellulose	9004-57-3	Not Listed
• Eudragit L30 D	25212-88-8	Not Listed
• Polyethylene glycol 1450	25322-68-3	Not Listed
• Triethyl citrate	77-93-0	Not Listed
• Povidone K90	9003-39-8	Not Listed
• Colloidal silicon dioxide	7631-86-9	1 %
• Glyceryl behenate	77538-19-3	Not Listed
• Bupropion hydrobromide	905818-69-1	Not Listed

United States - California

Environment

U.S. - California - Proposition 65 - Carcinogens List

• Polyvinyl alcohol	9002-89-5	Not Listed
• Ethylcellulose	9004-57-3	Not Listed
• Eudragit L30 D	25212-88-8	Not Listed
• Polyethylene glycol 1450	25322-68-3	Not Listed
• Triethyl citrate	77-93-0	Not Listed
• Povidone K90	9003-39-8	Not Listed
• Colloidal silicon dioxide	7631-86-9	Not Listed
• Glyceryl behenate	77538-19-3	Not Listed
• Bupropion hydrobromide	905818-69-1	Not Listed

U.S. - California - Proposition 65 - Developmental Toxicity

• Polyvinyl alcohol	9002-89-5	Not Listed
• Ethylcellulose	9004-57-3	Not Listed
• Eudragit L30 D	25212-88-8	Not Listed
• Polyethylene glycol 1450	25322-68-3	Not Listed
• Triethyl citrate	77-93-0	Not Listed
• Povidone K90	9003-39-8	Not Listed
• Colloidal silicon dioxide	7631-86-9	Not Listed
• Glyceryl behenate	77538-19-3	Not Listed
• Bupropion hydrobromide	905818-69-1	Not Listed

U.S. - California - Proposition 65 - Reproductive Toxicity - Female

• Polyvinyl alcohol	9002-89-5	Not Listed
• Ethylcellulose	9004-57-3	Not Listed
• Eudragit L30 D	25212-88-8	Not Listed
• Polyethylene glycol 1450	25322-68-3	Not Listed
• Triethyl citrate	77-93-0	Not Listed
• Povidone K90	9003-39-8	Not Listed
• Colloidal silicon dioxide	7631-86-9	Not Listed
• Glyceryl behenate	77538-19-3	Not Listed
• Bupropion hydrobromide	905818-69-1	Not Listed

U.S. - California - Proposition 65 - Reproductive Toxicity - Male

• Polyvinyl alcohol	9002-89-5	Not Listed
• Ethylcellulose	9004-57-3	Not Listed
• Eudragit L30 D	25212-88-8	Not Listed
• Polyethylene glycol 1450	25322-68-3	Not Listed
• Triethyl citrate	77-93-0	Not Listed
• Povidone K90	9003-39-8	Not Listed
• Colloidal silicon dioxide	7631-86-9	Not Listed
• Glyceryl behenate	77538-19-3	Not Listed
• Bupropion hydrobromide	905818-69-1	Not Listed

Section 16 - Other Information

Revision Date
- 22/February/2016

Last Revision Date
- 22/February/2016

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- 22/February/2016

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