SAFETY DATA SHEET

FORFIVO XL 450mg Extended-Release Tablet

Prepared to U.S. OSHA, CMA, ANSI, Canadian WHMIS Standards, Australian WorkSafe, Japanese Industrial Standard JIS Z 7250:2000, and European Directives

1. PRODUCT IDENTIFICATION

1.1 TRADE NAME (AS LABELED):	**FORFIVO XL 450mg Extended-Release Tablet**
SYNONYMS:	Bupropion Hydrochloride Extended Release Tablets, 450mg
CAS#:	Mixture
1.2 PRODUCT USE:	Pharmaceutical – Used to control Hypertension
PRODUCT CODE:	
1.3 MANUFACTURE:	**Almatica Pharma Inc.**
ADDRESS:	10 Bloomfield Avenue, Bldg B, Pine Brook, NJ 07058
BUSINESS PHONE:	1-844-842-8672
FAX NUMBER:	1-973-807-1625
1.4 EMERGENCY PHONE NUMBER:	
EMERGENCY PHONE #:	1-844-842-8672
COMPANY WEB SITE INFORMATION:	www.alvogen.us.com
1.5 PREPARATION INFORMATION:	
DATE OF CURRENT REVISION:	January 4, 2017
DATE OF LAST REVISION:	New

2. HAZARD IDENTIFICATION

EMERGENCY OVERVIEW:

Product Description: This product is a yellow tablet with no odor.

Health Hazards: Intact Bupropion Hydrochloride Extended Release Tablets, 450mg are not considered to be a health hazard with normal handling. The contents of these tablets may be irritating to the eyes and skin. Effects of exposure to the contents may include tremors, drowsiness, and liver tissue changes.

Flammability Hazards: This product is non-flammable.

Reactivity Hazards: None known

Environmental Hazards: The Environmental effects of this product have not been investigated. Release of this product is not expected to have significant adverse effects in the aquatic environment.

US DOT SYMBOLS	CANADA (WHMIS) SYMBOLS	EUROPEAN and (GHS) Hazard Symbols
Non-Regulated Material	Complies with WHMIS 2015	

Signal Word: **Warning**

2.1 CLASSIFICATION OF SUBSTANCE OR MIXTURE IN ACCORDANCE WITH 29 CFR 1200 (OSHA HCS) AND THE EUROPEAN UNION DIRECTIVES:

This product does meet the definition of a hazardous substance or preparation as defined by 29 CFR 1910. 1200 AND the European Union Council Directives 67/548/EEC, 1999/45/EC, 1272/2008/EC and subsequent Directives.

EU HAZARD CLASSIFICATION OF INGREDIENTS PER DIRECTIVE 1272/2008/EC:

None of the ingredients are classified in Annex VI

Substances not listed either individually or in group entries must be self classified.

COMPONENT(S) CONTRIBUTING TO CLASSIFICATION(S):

All Ingredients

2.2 LABEL ELEMENTS:

GHS Hazard Classification(s):

Skin Irritant Category 3

Eye Irritant Category 2B

Hazard Statement(s):

H315: Causes skin irritation

H320: Causes eye irritation

Precautionary Statement(s):

P262: Do not get in eyes, on skin, or on clothing

P264: Wash hands thoroughly after handling

2.3 HEALTH HAZARDS OR RISKS FROM EXPOSURE:

SYMPTOMS OF OVEREXPOSURE BY ROUTE OF EXPOSURE: The most significant routes of exposure for this product are by ingestion, inhalation and skin or eye contact. Tablets are intended for human consumption under guidance of a physician. Tablets are not considered hazardous under normal handling procedures.

ACUTE: Contents of the tablet may be irritating to skin and eyes. Bupropion hydrochloride, the active ingredient, may cause burns or permanent tissue damage to the eyes. Contact dermatitis (rash) has been reported with occupational exposure to Bupropion hydrochloride. The most common adverse events reported with therapeutic administration include nausea, decreased appetite, anxiety, tremors, dizziness, and sweating. The most common signs and symptoms associated with non-fatal over-dosage were seizures, hallucinations, loss of consciousness, sinus tachycardia, and ECG changes.

CHRONIC: Effects of exposure to the contents may include tremors, drowsiness, and liver tissue changes.

TARGET ORGANS: Acute: Eye, Skin **Chronic**: Liver

3. COMPOSITION AND INFORMATION ON INGREDIENTS

Hazardous Ingredients:	WT%	CAS#	EINECS #	GHS Hazard Classification(s)
Bupropion Hydrochloride	54 – 66%	31677-93-7	250-759-9	H315: Skin Irritant Cat.2, H319:Eye Irritant Cat 2A, H412: Hazardous to Aquatic Environment Cat 3
Excipients				
Polyethylene oxide	5 – 15%	25322-68-3	500-038-2	H315: Skin Irritant Cat.2, H320:Eye Irritant Cat 2B,
Hydroxypropyl cellulose	5 – 15%	9004-64-2	618-388-0	H303: Acute oral Toxicity Cat 5
Povidone	2 – 4%	9003-39-8	618-363-4	Not Classified
Polyvinyl acetate	8 – 15%	9003-20-7	618-358-7	H303: Acute oral Toxicity Cat 5
Methacrylic acid copolymer (Eudragit)	1 – 5%	25086-15-1	607-538-0	Not Classified
Balance of other ingredients is less than 1% in concentration (or 0.1% for carcinogens, reproductive toxins, or respiratory sensitizers).				

NOTE: This product has been classified in accordance with the hazard criteria of the CFR and the SDS contains all the information required by the CFR, EU Directives and the Japanese Industrial Standard *JIS Z 7250: 2000*.

4. FIRST-AID MEASURES

4.1 DESCRIPTION OF FIRST AID MEASURES:

EYE CONTACT: If product enters the eyes, open eyes while under gentle running water for at least 15 minutes. Seek medical attention if irritation continues or blurred vision occurs.

SKIN CONTACT: If product contacts skin, wash skin thoroughly with soap and water after handling. Seek medical attention if irritation develops and persists.

INHALATION: If breathing becomes difficult, remove victim to fresh air. If necessary, use artificial respiration to support vital functions. Seek medical attention.

INGESTION: If product is swallowed, call physician or poison control center for most current information. If professional advice is not available, do not induce vomiting. Never induce vomiting or give diluents (milk or water) to someone who is unconscious, having convulsions, or who cannot swallow. Seek medical advice. Take a copy of the label and/or SDS with the victim to the health professional.

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: None known

4.2 SYMPTOMS AND EFFECTS, BOTH ACUTE AND DELAYED:

Repeated exposure to high levels may cause effect on the kidneys. May produce dizziness, headache, fatigue, diarrhoea and characteristic cough.

4.3 RECOMMENDATIONS TO PHYSICIANS: Treat symptoms and eliminate overexposure.

5. FIRE-FIGHTING MEASURES

5.1 FIRE EXTINGUISHING MATERIALS:

Use fire extinguishing methods below:

Water Spray: Yes Carbon Dioxide: Yes
Foam: Yes Dry Chemical: Yes
Halon: Yes Other: Any "C" Class

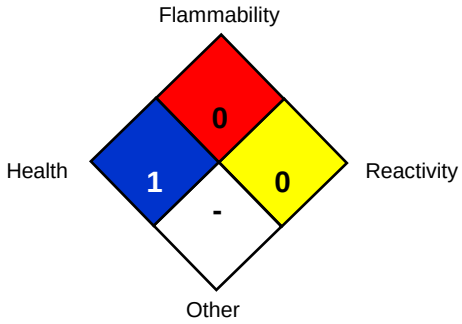
5.2 UNUSUAL FIRE AND EXPLOSION HAZARDS:

Explosion Sensitivity to Mechanical Impact: No
Explosion Sensitivity to Static Discharge: No

5.3 SPECIAL FIRE-FIGHTING PROCEDURES:

Incipient fire responders should wear eye protection. Structural firefighters must wear Self-Contained Breathing Apparatus and full protective equipment. Isolate materials not yet involved in the fire and protect personnel. Move containers from fire area if this can be done without risk; otherwise, cool with carefully applied water spray. If possible, prevent runoff water from entering storm drains, bodies of water, or other environmentally sensitive areas.

NFPA RATING SYSTEM



HMIS RATING SYSTEM

HAZARDOUS MATERIAL IDENTIFICATION SYSTEM

HEALTH HAZARD (BLUE)	1
FLAMMABILITY HAZARD (RED)	0
PHYSICAL HAZARD (YELLOW)	0

PROTECTIVE EQUIPMENT

EYES	RESPIRATORY	HANDS	BODY
	See Sect 8		See Sect 8

For Routine Industrial Use and Handling Applications

Hazard Scale: **0** = Minimal **1** = Slight **2** = Moderate **3** = Serious **4** = Severe * = Chronic hazard

6. ACCIDENTAL RELEASE MEASURES

6.1 PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES:

See section 8.2 for Exposure Controls.

6.2 ENVIRONMENTAL PRECAUTIONS:

None known

6.3 SPILL AND LEAK RESPONSE:

Pickup using a vacuum or sweep using minimal dust generating methods. (see Section 8 for specific handling precautions). Dispose of in accordance with applicable Federal, State, and local procedures (see Section 13, Disposal Considerations).

7. HANDLING and STORAGE

7.1 PRECAUTIONS FOR SAFE HANDLING:

Wash thoroughly after handling.

7.2 STORAGE AND HANDLING PRACTICES:

Store at 25°C (77°F). Excursions permitted to 15° to 30°C (59° to 86°F). Protect from light. Protect containers from physical damage.

7.3 SPECIFIC USES:

Used to control hypertension

8. EXPOSURE CONTROLS - PERSONAL PROTECTION

8.1 EXPOSURE PARAMETERS:

Chemical Name	CAS#	ACGIH TLV	OSHA TWA
Bupropion Hydrochloride	31677-93-7	Not Listed	Not Listed
Polyethylene oxide	25322-68-3	Not Listed	Not Listed
Hydroxypropyl cellulose	9004-64-2	Not Listed	Not Listed
Povidone	9003-39-8	Not Listed	Not Listed
Polyvinyl acetate	9003-20-7	Not Listed	Not Listed
Methacrylic acid copolymer (Eudragit)	25086-15-1	Not Listed	Not Listed

8.2 EXPOSURE CONTROLS:

VENTILATION AND ENGINEERING CONTROLS: Not Applicable

The following information on appropriate Personal Protective Equipment is provided to assist employers in complying with OSHA regulations found in 29 CFR Subpart I (beginning at 1910.132) or equivalent standard of Canada, or standards of EU member states (including EN 149 for respiratory PPE, and EN 166 for face/eye protection), and those of Japan. Please reference applicable regulations and standards for relevant details.

RESPIRATORY PROTECTION: Not normally required when using this product. If necessary, use only respiratory protection authorized in the U.S. Federal OSHA Respiratory Protection Standard (29 CFR 1910.134), equivalent U.S. State standards, Canadian CSA Standard Z94.4-93, the European Standard EN149, or EU member states.

EYE PROTECTION Not normally required with this product. If necessary, refer to U.S. OSHA 29 CFR 1910.133, Canadian Standards, and the European Standard EN166, Australian Standards, or relevant Japanese Standards.

SKIN PROTECTION: Not normally required with this product. If necessary, refer to U.S. OSHA 29 CFR 1910.138, the European Standard DIN EN 374, the appropriate Standards of Canada, Australian Standards, or relevant Japanese Standards.

9. PHYSICAL and CHEMICAL PROPERTIES

9.1 INFORMATION ON BASIC PHYSICAL AND CHEMICAL PROPERTIES:

APPEARANCE (Physical State) and COLOR: This product is a yellow tablet.
ODOR: None
ODOR THRESHOLD: Not Applicable
pH: Not Available
MELTING/FREEZING POINT: Not Available
BOILING POINT: Not Available
FLASH POINT: Not Applicable
EVAPORATION RATE (n-BuAc=1): Not Applicable
FLAMMABILITY (SOLID, GAS): Not Applicable
UPPER/LOWER FLAMMABILITY OR EXPLOSION LIMITS: Not Available
VAPOR PRESSURE (mm Hg @ 20°C (68°F): Not Applicable
VAPOR DENSITY: Not Applicable
RELATIVE DENSITY: Not Applicable
DENSITY: Not Available
SPECIFIC GRAVITY: Not Available
SOLUBILITY IN WATER: Not Available
WEIGHT PER GALLON: Not Applicable
PARTITION COEFFICENT (n-octanol/water): Not Applicable
AUTO-IGNITION TEMPERATURE: Not Available
DECOMPOSITION TEMPERATURE: Not Available
VISCOSITY: Not Applicable
VOC g/l / Lb/gal: Not Applicable

9.2 OTHER INFORMATION:

No additional information available.

10. STABILITY and REACTIVITY

10.1 REACTIVITY:

This product is not reactive.

10.2 STABILITY:

Stable under conditions of normal storage and use.

10.3 POSSIBILITY OF HAZARDOUS REACTIONS:

Will not occur

10.4 CONDITIONS TO AVOID:

None known

10.5 MATERIALS WITH WHICH SUBSTANCE IS INCOMPATIBLE:

Strong oxidizers

10.6 HAZARDOUS DECOMPOSITION PRODUCTS:

Decomposition products unknown.

11. TOXICOLOGICAL INFORMATION

11.1 INFORMATION ON TOXICOLOGICAL EFFECTS:

TOXICITY DATA:

No Toxicity data available

SUSPECTED CANCER AGENT: None of the ingredients within this product are found on the following lists: FEDERAL OSHA Z LIST, NTP, IARC, or CAL/OSHA and therefore are not considered to be, or suspected to be, cancer-causing agents by these agencies.

IRRITANCY OF PRODUCT: This product may be irritating to eyes and respiratory system.

SENSITIZATION TO THE PRODUCT: This product is not considered a respiratory system or skin sensitizer.

REPRODUCTIVE TOXICITY INFORMATION: Ingredients of this product may have adverse effects on the human reproductive system.

SPECIFIC TARGET ORGAN TOXICITY – SINGLE EXPOSURE: Reduces heart rate and lowers blood pressure.

SPECIFIC TARGET ORGAN TOXICITY – REPEATED EXPOSURE: Repeated exposure to high levels may cause effect on the kidneys. May produce dizziness, headache, fatigue, diarrhoea and characteristic cough.

ASPIRATION HAZARD: None

12. ECOLOGICAL INFORMATION

12.1 TOXICITY:

No toxicity data available.

12.2 PERSISTENCE AND DEGRADABILITY:

No specific data available on this product.

12.3 BIOACCUMULATIVE POTENTIAL:

No specific data available on this product.

12.4 MOBILITY IN SOIL:

No specific data available on this product.

12.5 RESULTS OF PBT ANDvPvB ASSESSMENT:

No specific data available on this product.

12.6 OTHER ADVERSE EFFECTS:

No specific data available on this product.

ALL WORK PRACTICES MUST BE AIMED AT ELIMINATING ENVIRONMENTAL CONTAMINATION.

12.7 WATER ENDANGERMENT CLASS:

Water endangering in accordance with EU Guideline 91/155-EWG. Not determined

13. DISPOSAL CONSIDERATIONS

13.1 WASTE TREATMENT METHODS:

Waste disposal must be in accordance with appropriate U.S. Federal, State, and local regulations, those of Canada, Australia, EU Member States and Japan.

13.2 EU Waste Code:

Not determined

14. TRANSPORTATION INFORMATION

US DOT, IATA, IMO, ADR:

U.S. DEPARTMENT OF TRANSPORTATION (DOT) SHIPPING REGULATIONS: This product is classified (per 49 CFR 172.101) by the U.S. Department of Transportation, as follows.

14.1 PROPER SHIPPING NAME:	Non-Regulated Material
14.2 HAZARD CLASS NUMBER and DESCRIPTION:	None
14.3 UN IDENTIFICATION NUMBER:	None
14.4 PACKING GROUP:	None
14.5 DOT LABEL(S) REQUIRED:	None
NORTH AMERICAN EMERGENCY RESPONSE GUIDEBOOK NUMBER:	None
RQ QUANTITY:	None

14.6 MARINE POLLUTANT: None of the components of this product are designated by the Department of Transportation to be Marine Pollutants (49 CFR 172.101, Appendix B).

14.7 SPECIAL PRECAUTIONS FOR USER:

Avoid exposure

14.8 INTERNATIONAL TRANSPORTION:

INTERNATIONAL AIR TRANSPORT ASSOCIATION SHIPPING INFORMATION (IATA): This product is not considered as dangerous goods.

INTERNATIONAL MARITIME ORGANIZATION SHIPPING INFORMATION (IMO): This product is not considered as dangerous goods.

14.9 TRANSPORT IN BULK ACCORDING TO ANNEX II OF MARPOL 73/78 AND IBC CODE:

EUROPEAN AGREEMENT CONCERNING THE INTERNATIONAL CARRIAGE OF DANGEROUS GOODS BY ROAD (ADR): This product is not considered by the United Nations Economic Commission for Europe to be dangerous goods.

15. REGULATORY INFORMATION

15.1 UNITED STATES REGULATIONS:

U.S. SARA REPORTING REQUIREMENTS: One of the components of this product are subject to the reporting requirements of Sections 302, 304, and 313 of Title III of the Superfund Amendments and Reauthorization Act.

SARA 313 Reporting: None

U.S. SARA THRESHOLD PLANNING QUANTITY: There are no specific Threshold Planning Quantities for the components of this product. The default Federal MSDS submission and inventory requirement filing threshold of 10,000 lbs (4,540 kg) therefore applies, per 40 CFR 370.20.

U.S. CERCLA REPORTABLE QUANTITY (RQ): None

U.S. TSCA INVENTORY STATUS: The components of this product are listed on the TSCA Inventory or are exempted form listing. Commercial use of this material is regulated by the FDA.

OTHER U.S. FEDERAL REGULATIONS: None

CALIFORNIA SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT (PROPOSITION 65): Ingredients within this product are not on the Proposition 65 Lists.

15.2 CANADIAN REGULATIONS:

CANADIAN DSL/NDSL INVENTORY STATUS: The components of this product are on the DSL Inventory, or are exempted from listing.

OTHER CANADIAN REGULATIONS: Not applicable.

CANADIAN ENVIRONMENTAL PROTECTION ACT (CEPA) PRIORITIES SUBSTANCES LISTS:

This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations and the MSDS contains all of the information required by those regulations.

CANADIAN WHMIS CLASSIFICATION and SYMBOLS: Complies with WHMIS 2015

15.3 EUROPEAN ECONOMIC COMMUNITY INFORMATION:

This product does meet the definition of a hazardous substance or preparation as defined by the European Union Council Directives 67/548/EEC, 1999/45/EC, 1272/2008/EC and subsequent Directives.

See Section 2 for full Details.

15.4 AUSTRALIAN INFORMATION FOR PRODUCT:

The components of this product are listed on the International Chemical Inventory list.

15.5 JAPANESE INFORMATION FOR PRODUCT:

JAPANESE MINISTER OF INTERNATIONAL TRADE AND INDUSTRY (MITI) STATUS:

The components of this product are not listed as Class I Specified Chemical Substances, Class II Specified Chemical Substances, or Designated Chemical Substances by the Japanese MITI.

JAPANESE ENCS INVENTORY:

The components of this product are on the ENCS Inventory as indicated in the section on International Chemical Inventories, below.

POISONOUS AND DELETERIOUS SUBSTANCES CONTROL LAW:

No component of this product is a listed Specified Poisonous Substance under the Poisonous and Deleterious Substances Control Law.

16. OTHER INFORMATION

PREPARED BY: Paul Eigbrett – (**GHS MSDS Compliance PLUS)**

DATE OF PRINTING: January 4, 2017

The information contained herein is believed to be accurate but is not warranted to be so. Data and calculations are based on information furnished by the manufacturer of the product and manufacturers of the components of the product. Users are advised to confirm in advance of the need that information is current, applicable and suited to the circumstances of use. Almatica Pharma Inc. assumes no responsibility for injury to vendee or third party person proximately caused by the material if reasonable safety procedures are no adhered to as stipulated in the data sheet. Furthermore, Almatica Pharma Inc. assumes no responsibility for injury caused by abnormal use of this material even if reasonable safety procedures are followed.

END OF SDS SHEET