MATERIAL SAFETY DATA SHEET
Fluoxetine Tablets, USP 60mg

SECTION 1 - PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME: Fluoxetine Tablets, USP 60mg
COMMON NAME: Fluoxetine Hydrochloride Tablets, USP 60mg
CHEMICAL NAME: Benzenepropanamine, N-methyl-gamma-[4-(trifluoromethyl)phenoxy]-hydrochloride
U.N. NUMBER: Not Applicable
U.N. DANGEROUS GOODS CLASS: Non-Regulated Material See section 14
MANUFACTURER’S NAME: Edgemont Pharmaceuticals, LLC
ADDRESS: 7000 North MoPac Expressway, Suite 200, Austin, TX 78731 USA
BUSINESS PHONE: 1-888-594-4332 (Product Information and reportable adverse reactions)
DATE OF PREPARATION: September 26, 2011
DATE OF LAST REVISION: New

SECTION 2 - HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW: This product is a white powder finished as coated tablets with no odor. Intact Fluoxetine Hydrochloride Tablets, USP 60mg are not considered to be a health hazard with normal handling. The contents of Fluoxetine Hydrochloride Tablets, USP 60mg may be irritating to the eyes and skin. Effects of exposure to the contents may include tremors, drowsiness, and liver tissue changes.

US DOT SYMBOLS
CANADA (WHMIS) SYMBOLS
EUROPEAN and (GHS) Hazard Symbols
Non-Regulated

EU LABELING AND CLASSIFICATION:
Classification of the substance or mixture according to Regulation (EC) No1272/2008 Annex 1
None of the ingredients are classified in the Annex I of Directive 67/548/EEC

GHS Hazard Classification(s):
Skin Irritant Category 3
Eye Irritant Category 2B
Hazardous to Aquatic Environment Category 3

Hazard Statement(s):
H315: Causes skin irritation
H320: Causes eye irritation
H412: Harmful to Aquatic Life with long lasting effects

Precautionary Statement(s):
P262: Do not get in eyes, on skin, or on clothing
P264: Wash hands thoroughly after handling
P273: Avoid release to the environment

EU HAZARD CLASSIFICATION PER DIRECTIVE 1999/45/EC:
Hazard Symbol(s):

HAZARD CLASSIFICATION:
[XI] Irritating, (N) Dangerous to the Environment

Risk Phrases:
R38 Irritating to skin
R41 Risk of serious damage to eyes.
R51/53: Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment,

Safety Phrases:
S26: In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S36/37/38: Wear suitable protective clothing, gloves and eye/face protection.
S45: In case you feel unwell, seek medical advice immediately.
S61: Avoid release to the environment.

HEALTH HAZARDS OR RISKS FROM EXPOSURE:
ACUTE EFFECTS OF OVEREXPOSURE: Tablets are intended for human consumption under guidance of a physician. Tablets are not considered hazardous under normal handling procedures. Contents of the capsule or tablet may be irritating to skin and eyes. Fluoxetine hydrochloride, the active ingredient, may cause burns or permanent tissue damage.
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Fluoxetine Tablets, USP 60mg

to the eyes. Contact dermatitis (rash) has been reported with occupational exposure to fluoxetinehydrochloride. The most common adverse events reported with therapeutic administration include nausea, decreased appetite, anxiety, tremors, drowsiness, and sweating. The most common signs and symptoms associated with non-fatal overdosage were seizures, drowsiness, nausea, increased heart rate, and vomiting.

CHRONIC: None Known.

TARGET ORGANS: ACUTE: Eye, skin

SECTION 3 - COMPOSITION and INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>HAZARDOUS INGREDIENTS</th>
<th>CAS #</th>
<th>EINECS #</th>
<th>ICSC #</th>
<th>WT %</th>
<th>HAZARD CLASSIFICATION; RISK PHRASES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Excipients</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mannitol</td>
<td>87-78-5</td>
<td>201-770-2</td>
<td>Not Listed</td>
<td>25 – 35%</td>
<td>HAZARD CLASSIFICATION: None RISK PHRASES: None</td>
</tr>
<tr>
<td>Cellulose, Microcrystalline</td>
<td>9004-34-6</td>
<td>232-674-9</td>
<td>Not Listed</td>
<td>20 – 30%</td>
<td>HAZARD CLASSIFICATION: None RISK PHRASES: None</td>
</tr>
<tr>
<td>Maize Starch</td>
<td>9005-25-8</td>
<td>232-679-6</td>
<td>1553</td>
<td>15 – 25%</td>
<td>HAZARD CLASSIFICATION: None RISK PHRASES: None</td>
</tr>
</tbody>
</table>

Balance of other ingredients are non-hazardous or less than 1% in concentration (or 0.1% for carcinogens, reproductive toxins, or respiratory sensitizers).

NOTE: ALL WHMIS required information is included in appropriate sections based on the ANSI Z400.1-2004 format. This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all the information required by the CPR, EU Directives and the Japanese Industrial Standard JIS Z 7250: 2000.

SECTION 4 - FIRST-AID MEASURES

Contaminated individuals of chemical exposure must be taken for medical attention if any adverse effect occurs. Rescuers should be taken for medical attention, if necessary. Take copy of label and MSDS to health professional with contaminated individual.

EYE CONTACT: If product enters the eyes, open eyes while under gentle running water for at least 15 minutes. Seek medical attention.

SKIN CONTACT: Wash skin thoroughly 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 if breathing difficulty continues.

INGESTION: If product is inadvertently 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 MSDS with the victim to the health professional.

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: Acute overdose after sustained therapeutic exposure has resulted in seizures. The potential for aggravation of a seizure disorder has not been ruled out.

RECOMMENDATIONS TO PHYSICIANS: Treat symptoms and reduce over-exposure.

SECTION 5 - FIRE-FIGHTING MEASURES

FLASH POINT: Not Applicable
AUTOIGNITION TEMPERATURE: Not Applicable
FLAMMABLE LIMITS (in air by volume, %): Lower (LEL): NA Upper (UEL): NA
FIRE EXTINGUISHING MATERIALS: Carbon dioxide, foam, dry chemical, halon, or water spray.
UNUSUAL FIRE AND EXPLOSION HAZARDS: This product is non-flammable. As a finely divided material, may form dust mixtures in air which could explode if subjected to an ignition source.

Explosion Sensitivity to Static Discharge: Not Sensitive.
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

<table>
<thead>
<tr>
<th>Flammability</th>
<th>Health</th>
<th>Reactivity</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>3</td>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>

HMIS RATING SYSTEM

| HEALTH HAZARD (BLUE) | 3 |
| FLAMMABILITY HAZARD (RED) | 1 |
| PHYSICAL HAZARD (YELLOW) | 0 |

PROTECTIVE EQUIPMENT

EYES: See Sect 8
RESPIRATORY: See Sect 8
HANdS: See Sect 8
BODY: See Sect 8

For Routine Industrial Use and Handling Applications

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

SECTION 6 - ACCIDENTAL RELEASE MEASURES

SPILLS: Vacuum material with appropriate dust collection filter in place. Be aware of potential for dust explosion when using electrical equipment. If vacuum is not available, lightly mist material and remove by sweeping or wet wiping. Wear protective equipment, including eye protection, to avoid exposure (see Section 8 for specific handling precautions). Dispose of in accordance with applicable Federal, State, and local procedures (see Section 13, Disposal Considerations).

SECTION 7 - HANDLING and STORAGE

WORK PRACTICES AND HYGIENE PRACTICES: As with all chemicals, avoid getting this product ON YOU or IN YOU. Wash thoroughly after handling this product. Do not eat, drink, smoke, or apply cosmetics while handling this product.

STORAGE AND HANDLING PRACTICES: Containers of this product must be properly labeled. Store containers in a cool, dry location. Controlled Room Temperature: 15 to 30 C (59 to 86 F).

SECTION 8 - EXPOSURE CONTROLS - PERSONAL PROTECTION

EXPOSURE LIMITS/GUIDELINES:

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS#</th>
<th>ACGIH TWA</th>
<th>OSHA TWA</th>
<th>SWA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluoxetine Hydrochloride</td>
<td>56296-78-7</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Mannitol</td>
<td>87-78-5</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Cellulose, Microcrystalline</td>
<td>9004-34-6</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Maize Starch</td>
<td>9005-25-8</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

Currently, International exposure limits are not established for the components of this product. Please check with competent authority in each country for the most recent limits in place.

VENTILATION AND ENGINEERING CONTROLS: Use with adequate ventilation to ensure exposure levels are maintained below the limits provided above. Use local exhaust ventilation to control airborne dust.
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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: Maintain airborne contaminant concentrations below guidelines listed above, if applicable. 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: Safety glasses or chemical goggles as appropriate to prevent eye contact. If necessary, refer to U.S. OSHA 29 CFR 1910.133 or appropriate Canadian Standards.

HAND PROTECTION: Use gloves as appropriate to prevent skin contact. If necessary, refer to U.S. OSHA 29 CFR 1910.138 or appropriate Standards of Canada.

BODY PROTECTION: Use body protection appropriate to prevent contact (e.g. lab coat, overalls). If necessary, refer to appropriate Standards of Canada, or appropriate Standards of the EU, Australian Standards, or relevant Japanese Standards.

SECTION 9 - PHYSICAL and CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>PROPERTY</th>
<th>PROPERTY</th>
</tr>
</thead>
<tbody>
<tr>
<td>PHYSICAL STATE:</td>
<td>Solid</td>
</tr>
<tr>
<td>APPEARANCE &amp; ODOR:</td>
<td>White powder or finished as coated tablets with no odor.</td>
</tr>
<tr>
<td>ODOR THRESHOLD (PPM):</td>
<td>None</td>
</tr>
<tr>
<td>VAPOR PRESSURE (mmHg):</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>VAPOR DENSITY (AIR=1):</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>EVAPORATION RATE (nBuAc = 1):</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>BOILING POINT (C°):</td>
<td>Not Available</td>
</tr>
<tr>
<td>FREEZING POINT (C°):</td>
<td>Not Available</td>
</tr>
<tr>
<td>pH:</td>
<td>Not Available</td>
</tr>
<tr>
<td>SPECIFIC GRAVITY 20°C: (WATER =1)</td>
<td>Not Available</td>
</tr>
<tr>
<td>SOLUBILITY IN WATER (%)</td>
<td>Soluble</td>
</tr>
</tbody>
</table>

SECTION 10 - STABILITY and REACTIVITY

STABILITY: Product is stable
DECOMPOSITION PRODUCTS: When heated to decomposition this product produces toxic fumes.
MATERIALS WITH WHICH SUBSTANCE IS INCOMPATIBLE: Strong oxidizing agents.
HAZARDOUS POLYMERIZATION: Will not occur.
CONDITIONS TO AVOID: Contact with incompatible materials.

SECTION 11 - TOXICOLOGICAL INFORMATION

TOXICITY DATA: Toxicity data is not available for mixture:
- CAS # 56296-78-7 Demal LD50 500 mg/kg Rabbit
SUSPECTED CANCER AGENT: None of the ingredients are found on the following lists: FEDERAL OSHA Z LIST, NTP, CAL/OSHA, IARC and therefore is not considered to be, nor suspected to be a cancer-causing agent by these agencies.
IRRITANCY OF PRODUCT: Contact with intact tablets is not considered to be a skin irritant.
SENSITIZATION OF PRODUCT: This product is not considered a sensitizer.
OTHER EFFECTS: Fluoxetine hydrochloride - In a juvenile toxicology study in rats, where the exposure period corresponds to human childhood and adolescence, administration of 30 mg/kg resulted in skeletal muscle necrosis.
REPRODUCTIVE TOXICITY INFORMATION: Fluoxetine hydrochloride - Two fertility studies conducted in adult rats indicated no adverse effects on fertility.
MUTAGENICITY: Fluoxetine hydrochloride - No genotoxic effects.

SECTION 12 - ECOLOGICAL INFORMATION

ALL WORK PRACTICES MUST BE AIMED AT ELIMINATING ENVIRONMENTAL CONTAMINATION.
ENVIRONMENTAL STABILITY: No environmental data for the mixture or formulation.
EFFECT OF MATERIAL ON PLANTS, ANIMALS AQUATIC LIFE: Fluoxetine hydrochloride - Moderately toxic to fish and highly toxic to invertebrates and green algae. No volatility expected. Low potential to bioaccumulate in aquatic organisms. Can be considered persistent due to low rates of biodegradation and hydrolysis.

SECTION 13 - DISPOSAL CONSIDERATIONS

PREPARING WASTES FOR DISPOSAL: Waste disposal must be in accordance with appropriate Federal, State, and local regulations, those of Canada, Australia, EU Member States and Japan.

SECTION 14 - TRANSPORTATION INFORMATION

US DOT; IATA; IMO; ADR:
THIS PRODUCT IS NOT HAZARDOUS AS DEFINED BY 49 CFR 172.101 BY THE U.S. DEPARTMENT OF TRANSPORTATION.

PROPER SHIPPING NAME: Non-Regulated Material
HAZARD CLASS NUMBER and DESCRIPTION: Not Applicable
UN IDENTIFICATION NUMBER: Not Applicable
PACKING GROUP: Not Applicable.
DOT LABEL(S) REQUIRED: Not Applicable
NORTH AMERICAN EMERGENCY RESPONSE GUIDEBOOK NUMBER (2004): Not Applicable
MARINE POLLUTANT: None of the ingredients are classified by the DOT as a Marine Pollutant (as defined by 49 CFR 172.101, Appendix B)

U.S. DEPARTMENT OF TRANSPORTATION (DOT) SHIPPING REGULATIONS:
This product is not classified as dangerous goods, per U.S. DOT regulations, under 49 CFR 172.101.

INTERNATIONAL AIR TRANSPORT ASSOCIATION (IATA):
This product is not classified as Dangerous Goods, by rules of IATA:

INTERNATIONAL MARITIME ORGANIZATION (IMO) DESIGNATION:
This product is not classified as Dangerous Goods by the International Maritime Organization.

EUROPEAN AGREEMENT CONCERNING THE INTERNATIONAL CARRIAGE OF DANGEROUS GOODS BY ROAD (ADR):
This material is considered to be an Environmentally Hazardous Substance according to the criteria set forth in the European Agreement Concerning the International Carriage of Dangerous Goods by Road (ADR) and is regulated as a Hazard Class 9 (UN3077 or UN3082) when shipping under ADR.

SECTION 15 - REGULATORY INFORMATION

UNITED STATES REGULATIONS
SARA REPORTING REQUIREMENTS: This product is not subject to the reporting requirements of Sections 302, 304 and 313 of Title III of the Superfund Amendments and Reauthorization Act., as follows: None
TSCA: All components in this product are listed on the US Toxic Substances Control Act (TSCA) inventory of chemicals.

SARA 311/312:
Acute Health: Yes Chronic Health: Yes Fire: Yes Reactivity: No

U.S. SARA THRESHOLD PLANNING QUANTITY: There are no specific Threshold Planning Quantities for this product. The default Federal MSDS submission and inventory requirement filing threshold of 10,000 lb (4,540 kg) may apply, per 40 CFR 370.20.
U.S. CERCLA REPORTABLE QUANTITY (RQ): None
CALIFORNIA SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT (PROPOSITION 65): None of the ingredients are on the California Proposition 65 lists.

CANADIAN REGULATIONS:
CANADIAN DSL/NDSL INVENTORY STATUS: All of the components of this product are on the DSL Inventory
CANADIAN ENVIRONMENTAL PROTECTION ACT (CEPA) PRIORITIES SUBSTANCES LISTS: No component of this product is on the CEPA First Priorities Substance Lists.
CANADIAN WHMIS CLASSIFICATION and SYMBOLS: This product is categorized as a Class D Division 2B Materials causing other toxic effects as per the Controlled Product Regulations

EUROPEAN ECONOMIC COMMUNITY INFORMATION:
EU LABELLING AND CLASSIFICATION:
Classification of the mixture according to Regulation (EC) No1272/2008. See section 2 for details.

AUSTRALIAN INFORMATION FOR PRODUCT:
AUSTRALIAN INVENTORY OF CHEMICAL SUBSTANCES (AICS) STATUS: All components of this product are listed on the AICS.

STANDARD FOR THE UNIFORM SCHEDULING OF DRUGS AND POISONS: Not applicable.

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.

INTERNATIONAL CHEMICAL INVENTORIES:
Listing of the components on individual country Chemical Inventories is as follows:
- Asia-Pac: Listed
- Australian Inventory of Chemical Substances (AICS): Listed
- Korean Existing Chemicals List (ECL): Listed
- Japanese Existing National Inventory of Chemical Substances (ENCS): Listed
- Philippines Inventory of Chemicals and Chemical Substances (PICCS): Listed
- Swiss Giftliste List of Toxic Substances: Listed
- U.S. TSCA: Listed

SECTION 16 - OTHER INFORMATION

PREPARED BY: Paul Eigbrett  MSDS Authoring PLUS

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