SAFETY DATA SHEETS

This SDS packet was issued with item:

078944623

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078940257 078944509 078944626

ScieGen Pharmaceuticals, Inc.
89 Arkay drive
Hauppauge, New York 11788
Tel: 631-434-2723
Fax: 631-357-3178

SAFETY DATA SHEET

Date: 06/02/2016

Generic Name: Fluoxetine Capsules, USP

Brand Equivalent: Prozac®

SECTION 1: IDENTIFICATION	
Product Name	Fluoxetine Capsules, USP 10 mg,20mg&40mg
Active substance	Fluoxetine Hydrochloride
Synonyms	N/A
Formula	$C_{17}H_{18}F_3NO$. HCl
Therapeutic Class:	Selective Serotonin Reuptake Inhibitor
Chemical Name	(±)-N-methyl-3-phenyl-3-[(α,α,α-trifluoro-p-tolyl)oxy]propylamine hydrochloride
Chemical Class	Phenylpropylamine
How Supplied	10 mg capsules are Opaque light blue colored cap and Opaque light orange colored body imprinted “SG” on cap and “113” on body with black ink. 20 mg capsules are Opaque light blue colored cap and Opaque light green colored body imprinted “SG” on cap and “114” on body with black ink. 40 mg capsules are Opaque Light Blue Colored Cap and Opaque white colored Body imprinted with **“SG”** on Cap and “**115**” on Body with black ink
Manufacturer Name & Address	ScieGen Pharmaceuticals, Inc. 89 Arkay drive, Hauppauge, NY 11788.
Telephone No.	631-434-2723

ScieGen Pharmaceuticals, Inc.
89 Arkay drive
Hauppauge, New York 11788
Tel: 631-434-2723
Fax: 631-357-3178

2. HAZARDS IDENTIFICATION:

GLOBAL HARMONIZATION AND EU CLP REGULATION (EC) 1272/2008 LABELING AND CLASSIFICATION: According to Article 1, item 5 (a) of CLP Regulation (EC) 1272/2008, medicinal products in the finished state for human use, as defined in 2001/83/EC, are excepted from classification and other criteria of 1272/2008.

EU LABELING/CLASSIFICATION: According to Article 1 of European Union Council Directive 92/32/EEC, medical products in the finished state for human use (as defined by European Union Council Directives 67/548/EEC and 87/21/EEC) are not subject to the regulations and administrative provisions of European Union Council Directive 92/32/EEC. **EMERGENCY OVERVIEW: Product Description:** This product consists of a hard gelatin capsules in color combinations noted in Section 1 or blue oval tablets. **Health Hazards:** In the workplace, exposure from dusts of capsules or tablets has the potential for irritation of contaminated skin or eyes. Non-therapeutic ingestion may be harmful. May cause adverse central nervous system effects. Chronic ingestion may cause serious or fatal systemic toxicity. Ingestion may cause allergic reactions. In therapeutic use, the most common adverse effects have been headache, difficulty concentrating, memory impairment, confusion, weakness, and unsteadiness. As a selective serotonin reuptake inhibitor, this material may cause harm to the fetus. These effects may be possible as a result of workplace exposure. See Section 11 (Toxicological Information) for more information on possible therapeutic use effects. **Flammability Hazards:** This product is combustible and can ignite if highly heated or if exposed to direct flame. When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds (including carbon and nitrogen oxides). **Reactivity Hazards:** This product is not reactive. **Environmental Hazards:** May cause harm to aquatic organisms if accidentally released. All environmental release should be avoided. **Emergency Recommendations:** Emergency responders must wear personal protective equipment suitable for the situation to which they are responding.

ScieGen Pharmaceuticals, Inc.
89 Arkay drive
Hauppauge, New York 11788
Tel: 631-434-2723
Fax: 631-357-3178

3. Composition/Information on ingredients		
Components	**CAS-No**	**Concentration (%w/w)**
Fluoxetine Hydrochloride	56296-78-7	8.94
Pregelatinized Starch, NF (Starch 1500)	9005-25-8	*
Colloidal silicon dioxide, NF (Aerosil 200 Pharma)	7631-86-9	*

* Proprietary, In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

4. FIRST AID MEASURES	
Eye contact	In case of eye contact, remove contact lens and rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Get medical attention immediately.
Skin contact	Immediately flush skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if irritation develops and persists. Wash contaminated clothing before reuse.
Inhalation	Move to fresh air. Oxygen or artificial respiration if needed. Get medical attention immediately.
Ingestion	Give several glasses of water. Never give anything by mouth to a victim who is unconscious or is having convulsions. Call a physician or poison control center immediately.
Most important symptoms/effects, acute and delayed	Causes eye burns. May cause drowsiness or dizziness. Increased heart rate. Seizures. May cause damage to the liver.
Indication of immediate medical attention and special treatment needed	Fluoxetine Hydrochloride - Cardiac and vital signs monitoring is recommended, along with general symptomatic and supportive measures. No specific antidote is known. Forced diuresis, dialysis, haemoperfusion, and exchange transfusion are unlikely to be of benefit. In limited human overdose experience, seizures have been reported. Appropriate seizure precautions are advised for any patient regularly taking fluoxetine who has been exposed to an acute overdose. Based on experience in animals, which may not be relevant to humans, fluoxetine-induced seizures that fail to remit spontaneously may respond to diazepam.
General information	In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

ScieGen Pharmaceuticals, Inc.
89 Arkay drive
Hauppauge, New York 11788
Tel: 631-434-2723
Fax: 631-357-3178

5. FIRE-FIGHTING MEASURES	
Suitable extinguishing media	Water. Carbon dioxide (CO2). Dry chemical.
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	Hazardous decomposition products formed under fire conditions.
Special protective equipment and precautions for firefighters	Wear self-contained breathing apparatus and protective clothing.

6. ACCIDENTAL RELEASE MEASURES	
Personal precautions, protective equipment and emergency procedures	Wear suitable protective clothing, gloves and eye/face protection. Do not breathe dust. See Section 8 of the SDS for Personal Protective Equipment.
Methods and materials for containment and cleaning up	The following are recommended for manufacturing or other situations where exposure to contents may occur. Do not sweep. 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/wet material and remove by mopping or wet wiping.

7. HANDLING AND STORAGE	
Precautions for safe handling	All employees who handle this material should be thoroughly trained to handle it safely. Do not eat or drink while handling this material. Ensure this material is used with adequate ventilation. Appropriate personal protective equipment must be worn (see Section 8, Exposure Controls - Personal Protection).
Conditions for safe storage, including any incompatibilities	Containers of this material must be properly labeled. Recommended Storage Temperature: 20-25°C (68-77°F). Empty containers may contain residual material; therefore, empty containers should be handled with care and disposed of properly.
Specific End Use	This is a human pharmaceutical
Protective Practices During Maintainence Of Contaminated Equipment	When cleaning non-disposable equipment, wear appropriate personal protective equipment.

ScieGen Pharmaceuticals, Inc.
89 Arkay drive
Hauppauge, New York 11788
Tel: 631-434-2723
Fax: 631-357-3178

8. Exposure controls/Personal protection	
Exposure Limits/Control Parameters: Ventillation And Engineering Controls	Use with adequate ventilation. Follow standard operating procedures and requirements for handling this product. Ensure eyewash stations and deluge showers are available and accessible in areas where this product is used.
Workplace Exposure Limits/ Control Parameters	There are no occupational exposure limits for this product.
Respiratory Protection	None needed for normal handling of this product. For large spill response or tasks involving generation of aerosols, use the appropriate Self-Contained Breathing Apparatus (SCBA) pressure-demand or other positive-pressure mode.
Eye/face protection	Wear splash goggles or safety glasses as appropriate for the task.
Skin protection	Use appropriate protective clothing for the task (e.g., lab coat, etc.).
Hand protection	Wear nitrile or other appropriate gloves to avoid contact and/or absorption of the product. Use double gloves for spill response.

ScieGen Pharmaceuticals, Inc.
89 Arkay drive
Hauppauge, New York 11788
Tel: 631-434-2723
Fax: 631-357-3178

9. PHYSICAL AND CHEMICAL PROPERTIES	
General Information	
Appearance **Physical State** **Color**	 Capsule As described in Section 1.
Odour **Odour** **Odor Threshold**	 Practically odorless Not applicable.
pH	Not available
Other information **Bulk density**	 Not available
Evaporation rate	Not available
Melting point/freezing point	159°C (318.2°F) Fluoxetine Hydrochloride
BOILING POINT @ 760 mmHg	395.1°C (743.2°F) Fluoxetine Hydrochloride
Flash point	Not applicable
Flammability limit – lower (%)	Not available.
Flammability limit – upper (%)	Not available.
Explosive limit - lower (%)	Not available
Explosive limit - upper (%)	Not available
Vapor pressure	Not available
Vapor density	No data available.
Relative Density	Not available
Solubility (water)	Soluble in water @ 25°C: 14 mg/mL Fluoxetine Hydrochloride
Partition coefficient **(n-octanol/water)**	0.930 (pH 5) Fluoxetine Hydrochloride 1.780 (pH 7) Fluoxetine Hydrochloride 2.630 (pH 9) Fluoxetine Hydrochloride
Auto-ignition temperature	Not available
Decomposition temperature	Not available
Viscosity	Not available
Other information **Explosive properties**	Not explosive
Oxidizing properties	The substance or mixture is not classified as oxidizing.

ScieGen Pharmaceuticals, Inc.
89 Arkay drive
Hauppauge, New York 11788
Tel: 631-434-2723
Fax: 631-357-3178

10. Stability and Reactivity	
Reactivity	Not water reactive
Chemical Stability	Stable under normal conditions
Possibility of hazardous reactions	Hazardous polymerization does not occur.
Conditions to avoid	None known.
Hazardous Decomposition products	Hazardous decomposition products formed under fire conditions.
Incompatible materials	Strong oxidizing agents.

11. Toxicological Information	
Symptoms Of Exposure By Route Of Exposure	The main expected routes of occupational exposure to this product are via inhalation of dusts, eye and skin contact. Exposure may cause allergic reaction. Exposure may also cause effects described under 'Other Potential Health Effects'.
Inhalation	Dusts may irritate the nose and upper respiratory system. Symptoms may include sneezing, coughing, and nasal congestion.
Contact With Skin or Eyes	Mild irritation possible. Symptoms may include itching and redness and swelling
Skin Absorbtion	No information available.
Ingestion	May be harmful or toxic. May irritate the mouth, throat, and gastrointestinal system
Injection	Not a likely route of exposure.
Aspiration hazard	No aspiration toxicity classification
Carcinogenicity	Due to lack of data the classification is not possible. This material is not considered to be a carcinogen by IARC, NTP, or OSHA
Reproductive Toxicity	Due to lack of data the classification is not possible
Developmental Toxicity	Due to lack of data the classification is not possible
Pharmacokinetics/Toxicokinetics	Due to lack of data the classification is not possible
Other Toxicity Information	Due to lack of data the classification is not possible

ScieGen Pharmaceuticals, Inc.
89 Arkay drive
Hauppauge, New York 11788
Tel: 631-434-2723
Fax: 631-357-3178

12. Ecological Information	
Ecotoxicity	This product may be harmful or fatal to contaminated plant and animal-life (especially if large quantities are released). This product has not been tested for aquatic toxicity.
Persistence and degradability	This product has not been tested for persistence and biodegradability. No predicted values are available.
Bioaccumulative potential	This product has not been tested for bio-accumulation potential.
Mobility in soil	This product has not been tested for mobility in soils.
Other adverse effects	The components of this product are not listed as having ozone depletion potential.

13. Disposal considerations	
Disposal instructions	Dispose of contents/container in accordance with local/regional/national/international regulations.
Precautions to be followed during waste handling	Wear proper protective equipment when handling waste materials

ScieGen Pharmaceuticals, Inc.
89 Arkay drive
Hauppauge, New York 11788
Tel: 631-434-2723
Fax: 631-357-3178

14. Transport Information	
U.S. Department of Transportation	This product is NOT classified as dangerous goods, per U.S. DOT regulations, under 49 CFR 172.101
Transport Canada Transportation of Dangerous Goods Regulations	This material does not meet the criteria of classification of Dangerous Goods, per regulations of Transport Canada
International Air Transport Association (IATA):	This product does not meet the criteria as Dangerous Goods, per rules of IATA
International Maritime Organization Designation (IMO)	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)	Does not meet the criteria as Dangerous Goods of the United Nations Economic Commission for Europe.
Transport in Bulk according to the IBC CODE	Not applicable.
Environmental hazards	This product does not meet the criteria of environmentally hazardous according to the criteria of the UN Model Regulations (as reflected in the IMDG Code, ADR, RID, and ADN) and no component is not specifically listed in Annex III under MARPOL 73/78

ScieGen Pharmaceuticals, Inc.
89 Arkay drive
Hauppauge, New York 11788
Tel: 631-434-2723
Fax: 631-357-3178

15. Regulatory Information	
U.S. Sara Reporting Requirements	The components of this product are not subject to the reporting requirements of Sections 302, 304, and 313 of Title III of the Superfund Amendments and Reauthorization Act.
U.S. SARA Threshhold Planning Quantity	There are no specific Threshold Planning Quantities for components of this product. The default Federal SDS submission and inventory requirement filing threshold of 10,000 lb (4,540 kg) may apply, per 40 CFR 370.20.
U.S. SARA Hazard Categories (Section 311/312, 40 CFR 370-21):	ACUTE: Yes; CHRONIC: Yes; FIRE: No; REACTIVE: No; SUDDEN RELEASE: No
U.S. CERCLA Reportable Quantity (RQ):	Not applicable.
U.S. TSCA Inventory status	This product is regulated under Food and Drug Administration standards; this product is not subject to requirements under TSCA.
OTHER U.S. Federal Regulations	Under the Hazard Communication Standard (HCS), Section (b)(5)(ii) drugs are subject to labeling requirements by the FDA under the Federal Food, Drug and Cosmetic Act and are exempt from labeling provisions of the HCS; this section of the HCS exempts only labeling requirements and not requirements for a Safety Data Sheet for drugs.
California Safe Drinking water and Toxic Enforcement Act (PROPOSITION 65)	No component of this product is listed on the California Proposition 65 Lists

16. Other information	
Recommended Restrictions for Use:	Not available
Prepared on	*06/02/16*
Revision	00
Disclaimer	The above information is believed to be correct but should only be used as a guide. ScieGen Pharmaceuticals, Inc. disclaims any express or implied warranty as to the accuracy of the above information and shall not be held liable for any direct, incidental or consequential damages resulting from reliance on the above information.