Scientific Documentation

F1200, Fluoxetine Hydrochloride, USP

Not appropriate for regulatory submission. Please visit www.spectrumchemical.com or contact Tech Services for the most up-to-date information contained in this information package.

Spectrum Chemical Mfg Corp
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Ver4.06 20.October.2022

F1200, Fluoxetine Hydrochloride, USP

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Specification for Fluoxetine Hydrochloride, USP (F1200)

Item Number	F1200
Item	Fluoxetine Hydrochloride, USP
CAS Number	56296-78-7
Molecular Formula	$C_{17}H_{18}F_3NO \cdot HCl$
Molecular Weight	345.79
MDL Number	
Synonyms	(+/-)-N-Methyl-3-phenyl-3-[(alpha,alpha,alpha-trifluoro-p-tolyl)oxy]propylamine Hydrochloride

Test	Specification	
	Min	Max
ASSAY (ANHYDROUS BASIS)	98.0	102.0 %
WATER DETERMINATION		0.5 %
ELEMENTAL IMPURITIES	AS REPORTED	
ORGANIC IMPURITIES	TO PASS TEST	
IDENTIFICATION	TO PASS TEST	
EXPIRATION DATE		
DATE OF MANUFACTURE		
APPEARANCE		
RESIDUAL SOLVENTS	TO PASS TEST	

Spectrum Chemical Mfg Corp

Corporate Headquarters:
769 Jersey Ave.
New Brunswick, NJ 08901
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West Coast Facility:
14422 S. San Pedro St.
Gardena, CA 90248
310.516.8000

Certificate Of Analysis

Item Number	F1200	Lot Number	2LE0131
Item	Fluoxetine Hydrochloride, USP	Manufacturer Lot	2150003524
CAS Number	56296-78-7	Manufacturer Code	14523
Molecular Formula	$C_{17}H_{18}F_3NO•HCl$	Molecular Weight	345.79

TEST	SPECIFICATION		RESULT
	MIN	MAX	
ASSAY (ANHYDROUS BASIS)	98.0	102.0 %	100.1%
WATER DETERMINATION		0.5 %	<0.5%
ELEMENTAL IMPURITIES	AS REPORTED		COMPLIES WITH STANDARD
ORGANIC IMPURITIES	TO PASS TEST		PASSES TEST
IDENTIFICATION	TO PASS TEST		PASSES TEST
EXPIRATION DATE			15-DEC-2026
DATE OF MANUFACTURE			17-DEC-2021
APPEARANCE			WHITE CRYSTALLINE POWDER
RESIDUAL SOLVENTS	TO PASS TEST		PASSES TEST

Certificate of Analysis Results Entered By:

GHERRERA
Genaro Herrera
02-AUG-22 08:43:15

Certificate of Analysis Results Approved By:

AWILLIAMS
Allison Williams
02-AUG-22 08:59:44

Spectrum Chemical Mfg Corp
755 Jersey Avenue
New Brunswick 08901 NJ

All pharmaceutical ingredients are tested using current edition of applicable pharmacopeia.

Read and understand label and SDS before handling any chemicals. All Spectrum's chemicals are for manufacturing, processing, repacking or research purposes by experienced personnel only. It is the customer's responsibility to provide adequate hazardous material training and ensure that appropriate Personal Protective Equipment (PPE) is used before handling any chemical.

The Elemental Impurities standards implemented by USP and other Pharmaceutical Compendia reflect a growing understanding of the toxicology of trace levels of elemental impurities that can remain in drug substances originating from either raw materials or manufacturing processes. Identifying and quantifying impurities can be critical to predicting the best possible patient outcomes. Elemental Impurities has been a requirement of all products meeting USP/NF, EP and BP monographs since January 1, 2018. More information can be found in USP sections <232> Elemental Impurities – Limits and <233> Elemental Impurities – Procedures. Data for drug substances furnished by Spectrum Chemical Mfg. Corp can be used to ensure that patient daily exposures by oral administration to the selected elements are not exceeded in the formulation of pharmaceutical products.

Spectrum Chemical Mfg. Corp. repackages Active Pharmaceutical Ingredient chemicals provided by other manufacturers and suppliers. For traceability purposes, Spectrum's Certificate of Analysis contains an identifier code unique to each manufacturer or supplier, as well as the chemical's lot number provided on the original manufacturer Certificate of Analysis. This material is manufactured by Olon SpA at Via Livelli 1, Casaletto Lodigiano (Mairano), LO 26852, Italy (ITA). Copies of the original Certificate of Analysis are available upon request from your Spectrum Sales Representative or by calling Spectrum's Quality Department at 1-800-772-8786.

SAFETY DATA SHEET

Preparation Date: 1/15/2018 **Revision Date:** 1/15/2018 **Revision Number:** G1

1. IDENTIFICATION

Product identifier

Product code: F1200
Product Name: FLUOXETINE HYDROCHLORIDE, USP

Other means of identification
Synonyms: Prozac
Fluctin/Fluctine
Fluoxeren
(+)-N-Methyl-3-phenyl-3-[(alpha, alpha, alpha-trifluoro-para-toyl)oxy] propylamine hydrochloride
(+-)-Methyl-gamma-(4-(trifluoromethyl)phenoxy)benzenepropanamine hydrochloride
3-(p-Trifluoromethylphenoxy)-N-methyl-3-phenylpropylamine hydrochloride
N-Methyl-3-phenyl-3-[4-(trifluoromethyl)phenoxy] propylamine hydrochloride
Propylamine, N-methyl-3-phenyl-(p-trifluoromethylphenoxy)-, hydrochloride
CAS #: 59333-67-4
RTECS # UI4050000
CI#: Not available

Recommended use of the chemical and restrictions on use
Recommended use: Antidepressant. Medication. Drug.
Uses advised against No information available

Supplier:
Spectrum Chemical Mfg. Corp
14422 South San Pedro St.
Gardena, CA 90248
(310) 516-8000

Order Online At: https://www.spectrumchemical.com
Emergency telephone number Chemtrec 1-800-424-9300
Contact Person: Martin LaBenz (West Coast)
Contact Person: Ibad Tirmiz (East Coast)

2. HAZARDS IDENTIFICATION

Classification

This chemical is considered hazardous according to the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Considered a dangerous substance or mixture according to the Globally Harmonized System (GHS)

Acute toxicity - Oral	Category 4
Serious eye damage/eye irritation	Category 2A
Specific target organ toxicity (single exposure)	Category 3

Label elements

Warning

Hazard statements
Harmful if swallowed
Causes serious eye irritation
May cause respiratory irritation

Hazards not otherwise classified (HNOC)
Not Applicable

Other hazards
Not available

Precautionary Statements - Prevention
Wash face, hands and any exposed skin thoroughly after handling
Do not eat, drink or smoke when using this product
Wear eye/face protection
Avoid breathing dust/fume/gas/mist/vapors/spray
Use only outdoors or in a well-ventilated area

Precautionary Statements - Response

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.
IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER or doctor/physician if you feel unwell.
IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell
Rinse mouth

Precautionary Statements - Storage
Store in a well-ventilated place. Keep container tightly closed
Store locked up

Precautionary Statements - Disposal
Dispose of contents/container to an approved waste disposal plant

3. COMPOSITION/INFORMATION ON INGREDIENTS

Components	CAS-No.	Weight %
Fluoxetine Hydrochloride	56296-78-7	100

4. FIRST AID MEASURES

First aid measures

General Advice: National Capital Poison Center in the United States can provide assistance if you have a poison emergency and need to talk to a poison specialist. Call 1-800-222-1222.

Skin Contact: Wash off immediately with soap and plenty of water removing all contaminated clothing and shoes. Get medical attention if irritation develops. Consult a physician if necessary.

Eye Contact: Flush eyes with water for 15 minutes. Get medical attention. If symptoms persist, call a physician.

Inhalation: Move to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

Ingestion: Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person. Obtain medical attention.

Most important symptoms and effects, both acute and delayed

Symptoms

Causes serious eye irritation
Irritating to respiratory system
Ingestion may cause nausea, vomiting, and diarrhea
May cause dyspepsia
May cause taste perversion
Sweating
Dryness of mouth
Thirst
May cause impairment of sense of taste
May cause loss of appetite
Weight loss/gain
Skin rash
Central nervous system effects
Fatigue
Seizures
May cause drowsiness or dizziness
May cause personality and mood changes
Excitement
Tremors
Restlessness
Headache
Muscle weakness
May affect the cardiovascular system
Fast or slow heartbeat
Hypotension
It may affect the joints
May affect eyes/vision
Chest tightness or pain
Difficult/painful and/or frequent urination
May cause tinnitus
May affect the liver
It may affect the peripheral nervous system
Paresthesia (numbness and tingling of the extremities)
Peripheral neuropathy
It may affect the blood
May affect the urinary system

Indication of any immediate medical attention and special treatment needed

Notes to Physician: Treat symptomatically.

Protection of first-aiders
First-Aid Providers: Avoid exposure to blood or body fluids. Wear gloves and other necessary protective clothing. Dispose of contaminated clothing and equipment as bio-hazardous waste.

5. FIRE-FIGHTING MEASURES

Extinguishing Media

Suitable Extinguishing Media: Dry chemical. Carbon dioxide (CO2). Water spray, mist, or foam.

Unsuitable Extinguishing Media: No information available.

Specific hazards arising from the chemical

Hazardous Combustion Products: Carbon Monoxide, Carbon Dioxide. Nitrogen Oxides. Hydrogen chloride. Hydrogen fluoride.

Specific hazards: May be combustible at high temperatures.

Special Protective Actions for Firefighters

Specific Methods: No information available.

Special Protective Equipment for Firefighters: As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal Precautions: Ensure adequate ventilation. Keep people away from and upwind of spill/leak. Avoid contact with skin, eyes and clothing. Wear personal protective equipment. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Remove all sources of ignition.

Environmental precautions Prevent further leakage or spillage if safe to do so. Prevent product from entering drains. Prevent entry into waterways, sewers, basements or confined areas.

Methods and material for containment and cleaning up

Methods for containment Stop leak if you can do it without risk. Cover with plastic sheet to prevent spreading.

Methods for cleaning up Sweep up and shovel into suitable containers for disposal. Clean contaminated surface thoroughly.

7. HANDLING AND STORAGE

Precautions for safe handling

Technical Measures/Precautions:
Provide sufficient air exchange and/or exhaust in work rooms. Avoid dust formation. Keep away from incompatible materials.

Safe Handling Advice
Avoid contact with skin, eyes and clothing. Wear personal protective equipment. Use only in well-ventilated areas. Keep away from heat and sources of ignition. Do not ingest. Do not breathe dust. Handle in accordance with good industrial hygiene and safety practice.

Conditions for safe storage, including any incompatibilities

Technical Measures/Storage Conditions:
Keep container tightly closed. Keep in a well-ventilated place. Store at room temperature in the original container. Store away from incompatible materials.

Incompatible Materials:
Oxidizing agents

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

National occupational exposure limits

United States

Components	CAS-No.	OSHA	NIOSH	ACGIH	AIHA WEEL
Fluoxetine Hydrochloride	56296-78-7	None	None	None	None

Canada

Components	CAS-No.	Canada - Alberta	Canada - British Columbia	Canada - Ontario	Canada - Quebec
Fluoxetine Hydrochloride	56296-78-7	None	None	None	None

Australia and Mexico

Components	CAS-No.	Australia	Mexico
Fluoxetine Hydrochloride	56296-78-7	None	None

Appropriate engineering controls

Engineering measures to reduce exposure: Ensure adequate ventilation, especially in confined areas. Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Individual protection measures, such as personal protective equipment

Personal Protective Equipment

Eye protection: Goggles or Safety glasses with side-shields

Skin and body protection: Chemical resistant apron
Gloves
Long sleeved clothing

Respiratory protection: Effective dust mask. Use a dust respirator under conditions where exposure to the substance is apparent (e.g. generation of high concentration of dust (dust clouds) , inadequate ventilation, development of respiratory tract irritation), and engineering controls are not feasible. Be sure to use an approved/certified respirator or equivalent.

Hygiene measures: Avoid contact with skin, eyes and clothing. When using, do not eat, drink or smoke. Wash hands before breaks and immediately after handling the product.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state:
Solid

Appearance:
Crystalline powder.

Color:
White. Off-white.

Odor:
No information available.

Taste
No information available.

Formula:
C17H18F3NO.HCl

Molecular/Formula weight:
345.79 g/mol

Flammability:
No information available

Flashpoint (°C/°F):
No information available.

Flash Point Tested according to:
Not available

Autoignition Temperature (°C/°F):
No information available

Lower Explosion Limit (%):
No information available

Upper Explosion Limit (%):
No information available

Melting point/range(°C/°F):
158-159°C/316.4-318°F

Decomposition temperature(°C/°F):
No information available

Boiling point/range(°C/°F):
No information available

Bulk density:
No information available

Density (g/cm3):
No information available

Specific gravity:
No information available

pH:
4.5-6.5 (1%)

Vapor pressure @ 20°C (kPa):
0.0000034

Evaporation rate:
No information available

Vapor density:
No information available

VOC content (g/L):
No information available

Odor threshold (ppm):
No information available

Partition coefficient (n-octanol/water):
1.8

Viscosity:
No information available

Miscibility:
No information available

Solubility:
Slightly soluble in water
Very soluble in Methanol
Very soluble in Ethanol
Freely soluble in Chloroform
Freely soluble in Dimethyl Sulfoxide (DMSO)
Freely soluble in Acetone
Soluble in acetonitrile
Slightly soluble in dichloromethane
Sparingly soluble in Ethyl acetate
Practically insoluble in Toluene
Practically insoluble in Hexane
Practically insoluble in cyclohexane

10. STABILITY AND REACTIVITY

Reactivity
Reactive with oxidizing agents

Chemical stability

Stability: Stable under recommended storage conditions.

Possibility of Hazardous Reactions: Hazardous polymerization does not occur

Conditions to avoid: Heat. Incompatible materials.

Incompatible Materials: Oxidizing agents

Hazardous decomposition Carbon dioxide. Carbon monoxide. Hydrogen chloride. Hydrogen fluoride.

products: Nitrogen oxides (NOx).

Other Information
Corrosivity: No information available

Special Remarks on Corrosivity: No information available

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Principal Routes of Exposure:
Ingestion. Inhalation.

Acute Toxicity

Component Information

Fluoxetine Hydrochloride	
CAS-No.	56296-78-7

LD50/oral/rat = 452 mg/kg Oral LD50 Rat
LD50/oral/mouse = 248 mg/kg oral LD50 mouse
LD50/dermal/rabbit = No information available
LD50/dermal/rat = No information available
LC50/inhalation/rat = No information available
LC50/inhalation/mouse = No information available
Other LD50 or LC50information = No information available

Product Information

LD50/oral/rat =
VALUE- Acute Tox Oral = 458 mg/kg

LD50/oral/mouse =
Value - Acute Tox Oral = 248 mg/kg

LD50/dermal/rabbit
VALUE-Acute Tox Dermal = No information available

LD50/dermal/rat
VALUE -Acute Tox Dermal = No information available

LC50/inhalation/rat
VALUE-Vapor = No information available
VALUE-Gas = No information available
VALUE-Dust/Mist = No information available

LC50/Inhalation/mouse
VALUE-Vapor = No information available
VALUE - Gas = No information available
VALUE - Dust/Mist = No information available

Symptoms

Skin Contact: May cause skin irritation.

Eye Contact: Causes serious eye irritation.

Inhalation Irritating to respiratory system.

Ingestion Harmful if swallowed. May cause gastritis, dyspepsia, excessive sweating, sore throat, stuffy nose, sinus pain, dry mouth, thirst, increased salivation, taste perversion, tongue discoloration, fecal incontinence, stomatitis, dysphagia, eructation, esophagitis, gingivitis, melena (black tarry stools), nausea, disturbances in appetite (anorexia/weight loss or weight gain), diarrhea, vomiting, bloody diarrhea, colitis, duodenal or gastric ulcer, salivary gland enlargement, Hyponatremia, tinnitus, abnormal vision, decreases libido, changes is sexual ability, impotence. May also affect the liver and cause abnormal liver function tests, jaundice, hepatitis, liver tenderness. May also affect behavior/central nervous system/peripheral nervous system with symptoms such as dizziness, memory loss, anxiety, nervousness, anxiety, insomnia, abnormal dreams, agitation, restlessness, fatigue, drowsiness, confusion, delusions, hallucinations, akathisia, psychosis, aggressiveness, impulsiveness, paranoid reaction, panic attacks, depersonalization, apathy, emotional lability, euphoria, hostility, amnesia, antisocial reaction, hysteria, suicidal ideation, violent behavior, hypomania, mania, seizures, dizziness, asthenia and headaches, tremor, twitching, dysarthria, lightheadedness, abnormal gait, ataxia, buccoglossal syndrome, vertigo, paresthesia, hypesthesia, neuralgia, neuropathy, incoordination, neck rigidity, extrapyramidal syndrome, stupor, coma, carpal tunnel syndrome, dyskinesia, dystonia and other movement disorder. May also affect the endocrine system (pancreatitis, hypoglycemia, hypothyroidism, gout), cardiovascular system (chest pain, hypertension, syncope, hypotension (including postural hypotension), angina, pectoris, arrhythmia, tachycardia, bradycardia, ventricualr arrhythmia, myocardial infarction, cerebral ischemia, cerebral vascular accident, thrombophlebitis), blood (anemia, lymphadenopathy, hemorrhage, altered platelet function, bleeding time increased, leukocytosis, lymphocytosis, thrombocytopenia, thrombocytopenic purpura, thrombocythemia, petechia, purpura, sedimentation rate increased, aplastic anemia, pancytopenia, immune-related hemolytic anemia), urinary system (frequent micturation, urinary tract infection, urethal pain, urolithiasis, kidney calculus, urethritis, hematuria, albuminuria, polyuria). May also cause musculoskeletal system effects such as muscle pain, back pain, joint pain, arthritis, bone pain, bursitis, tenosynovitis. Although infrequent or rare, skin rash, acne, dermatitis, or other skin conditions may occur as well bronchitis, rhinitis, anaphylactoid events including asthma, bronchospasm, angioedema, and urticaria alone and in combination. Pulmonary events including inflammatory processes of varying histopathology and/or fibrosis, have been reported rarely. These events have occurred with dyspnea as the only preceding symptom.

Aspiration hazard No information available.

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Chronic Toxicity Skin: Contact dermatitis (rash) has been reported with occupational exposure to Fluoxetine hydrochloride. Ingestion: Prolonged or repeated ingestion may affect respiratory system(progressive development of dyspnea, lung infiltrates, and restrictive lung disease, consistent with hypersensitivity pneumonitis),behavior/central nervous system (symptoms similar to acute ingestion), metabolism and cause weight loss and hypokalemia. Hypokalemia may lead to cardiac conduction abnormalities. It may also affect the liver with symptoms similar to acute ingestion.

Sensitization: No information available.

Mutagenic Effects: No information available

Carcinogenic effects: Not considered carcinogenic.

Components	CAS-No.	IARC	ACGIH - Carcinogens	NTP	OSHA HCS - Carcinogens	Australia - Notifiable Carcinogenic Substances	Australia - Prohibited Carcinogenic Substances
Fluoxetine Hydrochloride	56296-78-7	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed

ACGIH (American Conference of Governmental Industrial Hygienists)

IARC (International Agency for Research on Cancer)

NTP (National Toxicology Program)

OSHA (Occupational Safety and Health Administration of the US Department of Labor)

Reproductive toxicity No data is available

Reproductive Effects: Excreted in maternal milk in human
Developmental Effects: May cause adverse developmental effects
Teratogenic Effects: No information available

Specific Target Organ Toxicity

STOT - single exposure Respiratory system.
STOT - repeated exposure No information available.
Target Organs: Cardiovascular system. Central nervous system. Liver. Kidneys. Musculoskeletal system (joints, tendons). Lungs. Endocrine System.

12. ECOLOGICAL INFORMATION

Ecotoxicity

Ecotoxicity effects: Aquatic environment.

Fluoxetine Hydrochloride - 56296-78-7
Freshwater Fish Species Data: 1.57 mg/L LC50 Oncorhynchus mykiss 96h
Water Flea Data: 0.94 mg/L EC50 Daphnia magna 48h

Persistence and degradability: No information available

Bioaccumulative potential: No information available.

Mobility: No information available.

13. DISPOSAL CONSIDERATIONS

Disposal Methods

Waste from residues / unused products:
Waste must be disposed of in accordance with Federal, State and Local regulation.

Contaminated packaging:
Empty containers should be taken for local recycling, recovery or waste disposal

Components	CAS-No.	RCRA - F Series Wastes	RCRA - K Series Wastes	RCRA - P Series Wastes	RCRA - U Series Wastes
Fluoxetine Hydrochloride	56296-78-7	None	None	None	None

14. TRANSPORT INFORMATION

DOT

UN-No:	UN3077
Proper Shipping Name:	Environmentally hazardous substance, solid, n.o.s. (fluoxetine hydrochloride)
Hazard Class:	9
Subsidiary Class	No information available
Packing group:	III
Emergency Response Guide Number	No information available
Marine Pollutant	No data available
DOT RQ (lbs):	No information available
Special Provisions	No Information available
Symbol(s):	[DOT]: (G) - Identifies proper shipping names for which one or more technical names of the hazardous material must be entered in parentheses, in association with the basic description.
Description:	UN3077,Environmentally hazardous substance, solid, n.o.s. ,9,PG III

TDG (Canada)

UN-No:	UN3077
Proper Shipping Name:	Environmentally hazardous substance, solid, n.o.s. (fluoxetine hydrochloride)
Hazard Class:	9
Subsidiary Risk:	No information available
Packing Group:	III
Marine Pollutant	No Information available
Description:	UN3077,ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.,9,PG III

ADR

UN-No:	UN3077
Proper Shipping Name:	Environmentally hazardous substance, solid, n.o.s. (fluoxetine hydrochloride)
Hazard Class:	9
Packing Group:	III
Subsidiary Risk:	No information available
Description:	UN3077 Environmentally hazardous substance, solid, n.o.s.,9,III

IMO / IMDG

UN-No:	UN3077
Proper Shipping Name:	Environmentally hazardous substance, solid, n.o.s. (fluoxetine hydrochloride)
Hazard Class:	9
Subsidiary Risk:	No information available
Packing Group:	III
Marine Pollutant	No information available
EMS:	F-A

RID

UN-No:	UN3077
Proper Shipping Name:	Environmentally hazardous substance, solid, n.o.s. (fluoxetine hydrochloride)
Hazard Class:	9
Subsidiary Risk:	No information available
Packing Group:	III
Description:	UN3077 Environmentally hazardous substance, solid, n.o.s.,9,III

ICAO

UN-No:	UN3077
Proper Shipping Name:	Environmentally hazardous substance, solid, n.o.s. (fluoxetine hydrochloride)
Hazard Class:	9

Subsidiary Risk: No information available
Packing Group: III
Description: UN3077,Environmentally hazardous substance, solid, n.o.s.,9,PG III

IATA
UN-No: UN3077
Proper Shipping Name: Environmentally hazardous substance, solid, n.o.s. (fluoxetine hydrochloride)
Hazard Class: 9
Subsidiary Risk: No information available
Packing Group: III
ERG Code: 9L
Special Provisions No information available
Description: UN3077,Environmentally hazardous substance, solid, n.o.s.,9,PG III

15. REGULATORY INFORMATION

International Inventories

Components	CAS-No.	U.S. TSCA	KOREA KECL	Philippines (PICCS)	Japan ENCS	CHINA	Australia (AICS)	EINECS-No.
Fluoxetine Hydrochloride	56296-78-7	Not Listed	Not present	Not present	Not present	Not present	Not present	Present 260-101-2

U.S. Regulations

California Prop. 65: Safe Drinking Water and Toxic Enforcement Act of 1986.

Chemicals Known to the State of California to Cause Cancer:
This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

Chemicals Known to the State of California to Cause Reproductive Toxicity:
This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

Components	CAS-No.	Carcinogen	Developmental Toxicity	Male Reproductive Toxicity	Female Reproductive Toxicity:
Fluoxetine Hydrochloride	56296-78-7	Not Listed	Not Listed	Not Listed	Not Listed

CERCLA/SARA

Components	CAS-No.	CERCLA - Hazardous Substances and their Reportable Quantities	Section 302 Extremely Hazardous Substances and TPQs	Section 302 Extremely Hazardous Substances and RQs	Section 313 - Chemical Category	Section 313 - Reporting de minimis
Fluoxetine Hydrochloride	56296-78-7	None	None	None	None	None

U.S. TSCA

Components	CAS-No.	TSCA Section 5(a)2 - Chemicals With Significant New Use Rules (SNURS)	TSCA 8(d) -Health and Safety Reporting
Fluoxetine Hydrochloride	56296-78-7	Not Applicable	Not Applicable

Canada

WHIMIS 2015 - GHS Classifications

WHMIS 2015 Hazard Classification The WHMIS 2015 classification of this product has not been validated or reviewed yet.

Information:

Canada Hazardous Products Regulation This product has been classified according to the hazard criteria of the HPR (Hazardous Products Regulation) and the SDS contains all of the information required by the HPR

WHMIS 1988 Hazard Class
The classification of this product has not been validated yet

Canada Controlled Products Regulation:
This product has been classified according to the hazard criteria of the CPR (Controlled Products Regulation) and the MSDS contains all of the information required by the CPR.

Inventory

Components	CAS-No.	Canada (DSL)	Canada (NDSL)
Fluoxetine Hydrochloride	56296-78-7	Not Listed	Not Listed

Components	CAS-No.	CEPA Schedule I - Toxic Substances
Fluoxetine Hydrochloride	56296-78-7	Not listed
Components	CAS-No.	CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting
Fluoxetine Hydrochloride	56296-78-7	Not listed

EU Classification

EU GHS - SV - CLP 1272/2008

Components	CAS-No.	EU GHS - SV - CLP (1272/2008)
Fluoxetine Hydrochloride	56296-78-7	No information

EU - CLP (1272/2008)

R-phrase(s)
R22 - Harmful if swallowed.
R36/37 - Irritating to eyes and respiratory system.

S -phrase(s)
S22 - Do not breathe dust.
S26 - In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S46 - If swallowed, seek medical advice immediately and show this container or label.

Components	CAS-No.	**Classification**	**Concentration Limits:**	**Safety Phrases**
Fluoxetine Hydrochloride	56296-78-7		No information	

The product is classified in accordance with Annex VI to Directive 67/548/EEC

Indication of danger:
Xn - Harmful.
Xi - Irritant.

16. OTHER INFORMATION

Preparation Date: 1/15/2018
Revision Date: 1/15/2018
Prepared by: Sonia Owen

Disclaimer:

All chemicals may pose unknown hazards and should be used with caution. This Safety Data Sheet (SDS) applies only to the material as packaged. If this product is combined with other materials, deteriorates, or becomes contaminated, it may pose hazards not mentioned in this SDS. The physical properties reported in this SDS are obtained from the literature and do not constitute product specifications. Information contained herein does not constitute a warranty, whether expressed or implied, as to the safety, merchantability or fitness of the goods for a particular purpose. Spectrum Chemicals & Laboratory Products, Inc. assumes no responsibility for results obtained or for incidental or consequential damages, including lost profits, arising from the use of these data. No warranty against infringement of any patent, copyright or trademark is made or implied. It shall be the user's responsibility to develop proper methods of handling and personal protection based on the actual conditions of use. While this SDS is based on technical data judged to be reliable, Spectrum assumes no responsibility for the completeness or accuracy of the information contained herein.

End of Safety Data Sheet

spectrum®

Certification of Compliance with current Good Manufacturing Practices

Dear Valued Customer:

Spectrum Chemical Mfg Corp certifies that the following product(s) is produced, processed, packaged and held in compliance with current Good Manufacturing Practices (cGMP) in accordance with the applicable parts of 21 CFR, parts 210 and 211 of the Code of Federal Regulations.

Catalog Number	Product Name
F1200	Fluoxetine Hydrochloride, USP

Spectrum is an FDA registered and inspected Drug Establishment. Our United States Food and Drug Administration (USFDA) Registration numbers are as follows:

Spectrum-Gardena, CA: 2020632
Spectrum-New Brunswick, NJ: 2246824

Thank you for your interest in Spectrum products. If we may be of further assistance, please feel free to contact the Quality Assurance department at 310-516-8000 or via email at qualityassurance@spectrumchemical.com

Sincerely,

Oralia Chavez
Quality Assurance Specialist

F1200, Fluoxetine Hydrochloride, USP

Source Statement

The above mentioned catalog item is manufactured by chemical synthesis. No animal or plant derived products are used in the manufacturing process.

BSE/TSE Statement

The above mentioned catalog item does not contain nor is manufactured using any animal derived products and is therefore, BSE/TSE free.

Allergen Statement

The above mentioned catalog item does not contain any of the following:

- Milk
- Egg
- Fish
- Shellfish
- Tree Nuts
- Wheat
- Peanuts
- Soy
- Cereals containing Gluten
- Celery
- Mustard
- Sesame Seed
- Corn
- Latex
- Sulfites > 10 ppm

GMO Statement

The above mentioned catalog item is manufactured without the use of genetically modified organisms and is therefore GMO free.

Melamine Statement

The above mentioned catalog does not use or add melamine to the manufacturing process and is considered melamine-free.

Nitrosamine Statement

Based on knowledge of the manufacturing process, nitrosamine impurities are not known or suspected to be present in this material.

Organic Compliance Statement

The above mentioned catalog item has not been produced using GMOs, irradiation, ethylene oxide (EtO) or sewage sludge.

Shelf Life Statement

The above-mentioned catalog item is typically assigned a shelf life of 60 months from the date of manufacture. The actual assigned shelf life for any specific lot should be referenced on the Certificate of Analysis.

Other Chemicals Statement

Spectrum does not have any reason to suspect the above mentioned catalog item contains any of the following chemicals. This product does not come into contact with these chemicals during packaging or storage:

- Aflatoxins
- Antibiotics
- Bisphenol A (BPA)
- CMR Substances
- Parabens
- Pesticides
- Phthalates
- Preservatives

spectrum®

RE: Elemental Impurities - Fluoxetine Hydrochloride, USP (Cat# F1200)

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above mentioned material complies with the USP<232>, <233> Elemental Impurities and the ICH Q3D Elemental Impurities Guideline. No Class 1, Class 2A, Class 2B or Class 3 elemental impurities are likely to be present. These substances are not used in the production process, are not intentionally added or known to be present in the above mentioned material.

This information is subject to change and is intended for risk assessment only. It is responsibility of the end user to evaluate suitability of any chemical for the intended use as well as to assess compound-specific limits of daily intake of metal impurities. For lot-specific information, please refer to the respective Certificate of Analysis.

If you have any further questions, please contact us by telephone at 1(800)772-8786 Option 2, or by email at TechServices@spectrumchemical.com.

Sincerely,

Technical Services
Spectrum Chemical Mfg. Corp.

This document has been produced electronically and is valid without a signature.

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RE: Residual Solvents - Fluoxetine Hydrochloride, USP (Cat# F1200)

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above mentioned catalog item complies with the requirements of USP <467> Residual Solvents and ICH Q3C Residual Solvents Guideline. The following solvents are likely to be present:

Residual Solvent	Class	Expected Concentration
Toluene	2	< 890 ppm
Acetone	3	< 5000 ppm

No Class 1 or other solvents are used or produced in the manufacturing process of this material.

For lot-specific information, please refer to the respective Certificate of Analysis.

If you have any further questions, please contact us by telephone at 1(800)772-8786 Option 2, or by email at TechServices@spectrumchemical.com.

Sincerely,

Technical Services
Spectrum Chemical Mfg. Corp.

This document has been produced electronically and is valid without a signature.

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Label Information

The Spectrum label presents technical and safety information in an easily understood format. Our technical specialists stay abreast of the latest requirements of the Globally Harmonized System for Classification and Labelling of Chemicals (GHS), as well as the Occupational Safety and Health Administration (OSHA), the Food and Drug Administration (FDA) and other government regulatory agencies in order to ensure compliance, accuracy and concise hazard communication. Below you will find a typical label example for this catalog item.

Exp. Date: 00-00-0000

4945212004

WARNING

• Harmful if swallowed • Causes serious eye irritation • May cause respiratory irritation.

• Do not eat, drink or smoke when using this product • Wear eye protection, face protection • Avoid breathing dust • Use only outdoors or in a well-ventilated area • Wash face, hands and any exposed skin thoroughly after handling.

FIRST AID: Call a POISON CENTER or physician if you feel unwell. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical attention. IF INHALED: Remove person to fresh air and keep comfortable for breathing. IF SWALLOWED: Rinse mouth.

KEEP FROM CHILDREN

F1200 **SIZ SY**

Fluoxetine Hydrochloride

{(±)-*N*-Methyl-3-phenyl-3-[(α,α,α-trifluoro-*p*-tolyl)oxy]propylamine Hydrochloride}

USP

CAS 56296-78-7

CAUTION: For manufacturing, processing, repacking, or for prescription compounding. Rx only.
Read and understand the label and Safety Data Sheet (SDS) prior to use.

DOT: UN3077, Environmentally hazardous substance, solid, n.o.s. (fluoxetine hydrochloride), 9, PG III

Chemical Emergency: (800)424-9300

www.SpectrumChemical.com

$C_{17}H_{18}F_3NO•HCl$ F.W. 345.79

Manufacturer/Supplier Code ..... ?
Manufacturer Lot Number ..... ?

Assay (Anhydrous Basis) 98.0-102.0%

MAXIMUM LIMITS

Water Determination 0.5%
Elemental Impurities ..... As reported
Organic Impurities (With 0.05% Reporting Threshold):
- Aminomethyl-1-Phenylpropanol 0.25%
- Fluoxetine Related Compound B 0.25%
- Fluoxetine Related Compound A 0.15%
- 4-Trifluoromethylphenol 0.10%
- Any Individual Unspecified Impurity 0.10%
- Total Impurities 0.5%

Residual Solvents ..... To pass test

WARNING: Cancer and Reproductive Harm-www.P65Warnings.ca.gov

Repackaged by Spectrum as:

B 9/11GHS-A ? Lot No. XQ####

Spectrum Chemical Mfg Corp

Corporate Headquarters:
769 Jersey Ave.
New Brunswick, NJ 08901
732.214.1300

West Coast Facility:
14422 S. San Pedro St.
Gardena, CA 90248
310.516.8000

spectrum®

RE: Lot Numbering System

Dear Valued Customer:

This letter is to inform you of Spectrum Chemicals and Laboratory Products' Lot Numbering System. The system is based on an alpha-numerical sequence which provides the month, year and location of production.

The lot numbering system utilized until 2010 is a sequence of **six characters**, two letters followed by four numbers. The first letter represents the year, for example, Y denotes 2009 and Z denotes 2010. The second letter represents the month and site, for example, A-L denotes January through December at Spectrum's Gardena, CA facility, while M-X denotes January through December at the New Brunswick, NJ facility. The following four numbers are sequentially assigned.

Example: ZI0928 = The 928th material produced in California in September 2010

The lot numbering system utilized for 2011 and forward, is a sequence of **seven characters**. The first character, a number, represents the production facility:

1 = Gardena, CA Facility
2 = New Brunswick, NJ Facility
3 = China Facility
4 = Pharmacy, NJ Facility

The second character, a letter, represents the year. For example, A denotes 2011 and B denotes 2012. The third character, a letter, represents the month, with A denoting January and L denoting December. The following four numbers are sequentially assigned.

Example: 2AA0706 = The 706th material produced in New Jersey in January 2011

Thank you for your interest with Spectrum products. Please feel free to contact us at 310-516-8000 or via email at quality_assurance@spectrumchemical.com if we may be of further assistance.

Sincerely,

Oralia Chavez,
Quality Assurance Specialist

CORPORATE HEADQUARTERS
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FAX 732.246.7132

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