

# Scientific Documentation

## Fluoxetine Hydrochloride, USP

Not appropriate for regulatory submission.

Please visit [www.spectrumchemical.com](http://www.spectrumchemical.com) or contact Tech Services for the most up-to-date information contained in this information package.

Spectrum Chemical Mfg Corp  
769 Jersey Avenue  
New Brunswick, NJ 08901  
Phone 732.214.1300



## **Table of Contents**

Product Specification  
Certificate of Analysis  
Safety Data Sheet (SDS)  
Certification of Current Good Manufacturing Practices (cGMP)  
Technical Statements  
Elemental Impurities Statement  
Residual Solvents Statement  
General Label Information – Sample Label

# Specification for Fluoxetine Hydrochloride, USP (F1200)

Item Number	F1200
Item	Fluoxetine Hydrochloride, USP
CAS Number	56296-78-7
Molecular Formula	C <sub>17</sub> H <sub>18</sub> F <sub>3</sub> NO•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*

<b>Corporate Headquarters:</b>	<b>West Coast Facility:</b>
769 Jersey Ave.	14422 S. San Pedro St.
New Brunswick, NJ 08901	Gardena, CA 90248
732.214.1300	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 <sub>17</sub> H <sub>18</sub> F <sub>3</sub> NO•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

Spectrum Chemical Mfg Corp  
755 Jersey Avenue  
New Brunswick 08901 NJ



Certificate of Analysis Results Approved By:

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

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

# spectrum®



Revision date 20-October-2022

Revision Number 2

## 1. Identification

### Product identifier

**Product Name** FLUOXETINE HYDROCHLORIDE, USP

### Other means of identification

**Product Code(s)** F1200

**UN/ID no** UN3077

**Synonyms** None

### Recommended use of the chemical and restrictions on use

**Recommended use** No information available

**Restrictions on use** No information available

### Details of the supplier of the safety data sheet

#### Supplier Address

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

### Emergency telephone number

**Emergency Telephone** Chemtrec 1-800-424-9300

## 2. Hazard(s) identification

### Classification

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

### Hazards not otherwise classified (HNOC)

Not applicable

### Label elements

#### Warning

#### Hazard statements

Harmful if swallowed  
Causes serious eye irritation  
May cause respiratory irritation



**Appearance** Crystalline powder

**Physical state** Solid

**Odor** No information 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 protection/ 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 if you feel unwell

IF SWALLOWED: Call a POISON CENTER or doctor 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

**Other information**

No information available.

### 3. Composition/information on ingredients

**Substance**

Chemical name	CAS No	Weight-%
Fluoxetine Hydrochloride	56296-78-7	100

### 4. First-aid measures

**Description of first aid measures**

**General advice**

Show this safety data sheet to the doctor in attendance.

**Inhalation**

Remove to fresh air. IF exposed or concerned: Get medical advice/attention.

**Eye contact**

Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Keep eye wide open while rinsing. Do not rub affected area. Get medical attention if irritation develops and persists.

**Skin contact**

Wash skin with soap and water.

**Ingestion**

Do NOT induce vomiting. Clean mouth with water and drink afterwards plenty of water. Never give anything by mouth to an unconscious person. Call a physician.

**Self-protection of the first aider**      Avoid contact with skin, eyes or clothing. Wear personal protective clothing (see section 8).

**Most important symptoms and effects, both acute and delayed**

**Symptoms**      May cause redness and tearing of the eyes. Burning sensation.

**Indication of any immediate medical attention and special treatment needed**

**Note to physicians**      Treat symptomatically.

## **5. Fire-fighting measures**

**Suitable Extinguishing Media**      Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

**Large Fire**      CAUTION: Use of water spray when fighting fire may be inefficient.

**Unsuitable extinguishing media**      Do not scatter spilled material with high pressure water streams.

**Specific hazards arising from the chemical**      No information available.

**Hazardous combustion products**      Carbon dioxide (CO<sub>2</sub>). Hydrocarbons. none. Flammable/toxic gases may accumulate in tanks and hopper cars.

**Explosion data**

**Sensitivity to mechanical impact**      none.

**Sensitivity to static discharge**      none.

**Special protective equipment for fire-fighters**      Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

## **6. Accidental release measures**

**Personal precautions, protective equipment and emergency procedures**

**Personal precautions**      Ensure adequate ventilation. Use personal protective equipment as required. Evacuate personnel to safe areas. Avoid contact with skin, eyes or clothing.

**Other information**      Refer to protective measures listed in Sections 7 and 8.

**Methods and material for containment and cleaning up**

**Methods for containment**      Prevent further leakage or spillage if safe to do so.

**Methods for cleaning up**      Pick up and transfer to properly labeled containers.

## **7. Handling and storage**

**Precautions for safe handling**

**Advice on safe handling**      Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product.

**Conditions for safe storage, including any incompatibilities**

**Storage Conditions**      Keep containers tightly closed in a dry, cool and well-ventilated place. Keep out of the reach of children.



## 8. Exposure controls/personal protection

### Control parameters

#### Exposure Limits

The following ingredients are the only ingredients of the product above the cut-off level (or level that contributes to the hazard classification of the mixture) which have an exposure limit applicable in the region for which this safety data sheet is intended or other recommended limit. At this time, the other relevant constituents have no known exposure limits from the sources listed here.

### Appropriate engineering controls

#### Engineering controls

Showers  
Eyewash stations  
Ventilation systems.

### Individual protection measures, such as personal protective equipment

#### Eye/face protection

If splashes are likely to occur, wear safety glasses with side-shields.

#### Hand protection

Wear suitable gloves.

#### Skin and body protection

Wear suitable protective clothing.

#### Respiratory protection

No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.

#### General hygiene considerations

Avoid contact with skin, eyes or clothing. Wear suitable gloves and eye/face protection. Do not eat, drink or smoke when using this product.

## 9. Physical and chemical properties

### Information on basic physical and chemical properties

Physical state	Solid
Appearance	Crystalline powder
Color	White to Off-White
Odor	No information available
Odor threshold	No information available

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
pH	4.5-6.5 (1%)	None known
Melting point / freezing point	159 °C / 318.2 °F	None known
Boiling point / boiling range	no data available	None known
Flash point	no data available	None known
Evaporation rate	no data available	None known
Flammability (solid, gas)	no data available	None known
Flammability Limit in Air		None known
Upper flammability or explosive limits	No data available	
Lower flammability or explosive limits	No data available	
Vapor pressure	No data available	None known
Vapor density	no data available	None known
Relative density	no data available	None known
Water solubility	Slightly soluble in water	None known
Solubility(ies)	Soluble in Dimethyl Sulfoxide	None known
Partition coefficient	No data available	None known
Autoignition temperature	no data available	None known
Decomposition temperature		None known
Kinematic viscosity	no data available	None known

Dynamic viscosity No data available None known

**Other information**

Explosive properties No information available  
Oxidizing properties No information available  
Softening point No information available  
Molecular weight No information available  
VOC Content (%) No information available  
Liquid Density No information available  
Bulk density No information available

## 10. Stability and reactivity

Reactivity No information available.  
Chemical stability Stable under normal conditions.  
Possibility of hazardous reactions None under normal processing.  
Conditions to avoid None known based on information supplied.  
Incompatible materials None known based on information supplied.  
Hazardous decomposition products None known based on information supplied.

## 11. Toxicological information

**Information on likely routes of exposure**

**Product Information**

**Inhalation** Specific test data for the substance or mixture is not available. May cause irritation of respiratory tract.

**Eye contact** Specific test data for the substance or mixture is not available. Causes serious eye irritation. (based on components). May cause redness, itching, and pain.

**Skin contact** Specific test data for the substance or mixture is not available. May cause irritation. Prolonged contact may cause redness and irritation.

**Ingestion** Specific test data for the substance or mixture is not available. Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea. Harmful if swallowed. (based on components).

**Symptoms related to the physical, chemical and toxicological characteristics**

**Symptoms** May cause redness and tearing of the eyes.

**Acute toxicity**

**Numerical measures of toxicity**

**Component Information**

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Fluoxetine Hydrochloride 56296-78-7	= 452 mg/kg ( Rat )	-	-

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

**Skin corrosion/irritation** May cause skin irritation.

<b>Serious eye damage/eye irritation</b>	Classification based on data available for ingredients. Causes serious eye irritation.
<b>Respiratory or skin sensitization</b>	No information available.
<b>Germ cell mutagenicity</b>	No information available.
<b>Reproductive toxicity</b>	No information available.
<b>STOT - single exposure</b>	No information available.
<b>STOT - repeated exposure</b>	No information available.
<b>Aspiration hazard</b>	No information available.
<b>Other adverse effects</b>	No information available.
<b>Interactive effects</b>	No information available.

## 12. Ecological information

### Ecotoxicity

Chemical name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Fluoxetine Hydrochloride 56296-78-7	-	1.57 mg/L LC50 Oncorhynchus mykiss 96h	-	0.94 mg/L EC50 Daphnia magna 48h

<b>Persistence and degradability</b>	No information available.
<b>Bioaccumulation</b>	Inherently biodegradable.

<b>Other adverse effects</b>	No information available.
------------------------------	---------------------------

## 13. Disposal considerations

### Waste treatment methods

<b>Waste from residues/unused products</b>	Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.
--	---

<b>Contaminated packaging</b>	Do not reuse empty containers.
-------------------------------	--------------------------------

## 14. Transport information

### DOT

<b>UN/ID no</b>	UN3077
<b>Proper Shipping Name:</b>	Environmentally hazardous substance, solid, n.o.s.
<b>Hazard class</b>	9
<b>Packing group:</b>	III
<b>Special Provisions</b>	146, 335, A112, B54, B120, IB8, IP3, N20, N91, T1, TP33, 8
<b>Marine Pollutant</b>	Severe Marine Pollutant
<b>Description:</b>	UN3077, Environmentally hazardous substance, solid, n.o.s., 9, III, Marine pollutant

### TDG

<b>UN-No:</b>	UN3077
<b>Proper Shipping Name:</b>	Environmentally hazardous substance, solid, n.o.s.
<b>Hazard class</b>	9
<b>Packing Group:</b>	III
<b>Special Provisions</b>	16, 99
<b>Description:</b>	UN3077, Environmentally hazardous substance, solid, n.o.s., 9, III

### MEX

<b>UN-No</b>	UN3077
<b>Proper Shipping Name</b>	Environmentally hazardous substance, solid, n.o.s.

<b>Hazard class</b>	9
<b>Special Provisions</b>	274, 331, 335
<b>Packing Group</b>	III
<b>Description</b>	UN3077, Environmentally hazardous substance, solid, n.o.s., 9, III

#### ICAO (air)

<b>UN-No:</b>	UN3077
<b>Proper Shipping Name:</b>	Environmentally hazardous substance, solid, n.o.s.
<b>Hazard class</b>	9
<b>Packing Group:</b>	III
<b>Special Provisions</b>	A97, A158, A179, A197, A215
<b>Description:</b>	UN3077, Environmentally hazardous substance, solid, n.o.s., 9, III

#### IATA

<b>UN number</b>	UN3077
<b>Proper Shipping Name:</b>	Environmentally hazardous substance, solid, n.o.s.
<b>Transport hazard class(es)</b>	9
<b>Packing group</b>	III
<b>ERG Code</b>	9L
<b>Special Provisions</b>	A97, A158, A179, A197, A215
<b>Description:</b>	UN3077, Environmentally hazardous substance, solid, n.o.s., 9, III

#### IMDG

<b>UN number</b>	UN3077
<b>Proper shipping name</b>	Environmentally hazardous substance, solid, n.o.s.
<b>Transport hazard class(es)</b>	9
<b>Packing group</b>	III
<b>EmS-No</b>	F-A, S-F
<b>Special Provisions</b>	274, 335, 966, 967, 969
<b>Marine pollutant</b>	P
<b>Description</b>	UN3077, Environmentally hazardous substance, solid, n.o.s., 9, III, Marine pollutant

#### RID

<b>UN number</b>	UN3077
<b>Proper Shipping Name:</b>	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
<b>Transport hazard class(es)</b>	9
<b>Packing group</b>	III
<b>Classification code</b>	M7
<b>Special Provisions</b>	274, 335, 375, 601
<b>Description:</b>	UN3077, ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S., 9, III
<b>Labels</b>	9

#### ADR

<b>UN number</b>	UN3077
<b>Proper Shipping Name:</b>	Environmentally hazardous substance, solid, n.o.s.
<b>Transport hazard class(es)</b>	9
<b>Packing group</b>	III
<b>Classification code</b>	M7
<b>Tunnel restriction code</b>	(-)
<b>Special Provisions</b>	274, 335, 601, 375
<b>Description:</b>	UN3077, Environmentally hazardous substance, solid, n.o.s., 9, III, (-)
<b>Labels</b>	9

#### ADN

<b>UN/ID No</b>	UN3077
<b>Proper shipping name</b>	Environmentally hazardous substance, solid, n.o.s.
<b>Transport hazard class(es)</b>	9
<b>Packing Group</b>	III
<b>Classification code</b>	M7
<b>Special Provisions</b>	274, 335, 375, 601
<b>Description</b>	UN3077, Environmentally hazardous substance, solid, n.o.s., 9, III
<b>Hazard label(s)</b>	9
<b>Equipment Requirements</b>	A, PP

### 15. Regulatory information

## **International Inventories**

<b>TSCA</b>	Complies
<b>DSL/NDL</b>	Does not Comply
<b>EINECS/ELINCS</b>	Complies
<b>ENCS</b>	This product complies with ENCS:
<b>IECSC</b>	This product does not comply with china:
<b>KECL</b>	Does not Comply
<b>PICCS</b>	Does not Comply
<b>AICS</b>	This product does not comply with AICS

### **Legend:**

**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory

**DSL/NDL** - Canadian Domestic Substances List/Non-Domestic Substances List

**EINECS/ELINCS** - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

**ENCS** - Japan Existing and New Chemical Substances

**IECSC** - China Inventory of Existing Chemical Substances

**KECL** - Korean Existing and Evaluated Chemical Substances

**PICCS** - Philippines Inventory of Chemicals and Chemical Substances

## **US Federal Regulations**

### **SARA 313**

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

### **SARA 311/312 Hazard Categories**

Should this product meet EPCRA 311/312 Tier reporting criteria at 40 CFR 370, refer to Section 2 of this SDS for appropriate classifications.

### **CWA (Clean Water Act)**

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

### **CERCLA**

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

## **US State Regulations**

### **California Proposition 65**

This product does not contain any Proposition 65 chemicals.

### **U.S. State Right-to-Know Regulations**

This product does not contain any substances regulated under applicable state right-to-know regulations

## **U.S. EPA Label Information**

**EPA Pesticide Registration Number** Not applicable

## **16. Other information**

**NFPA****Health hazards** 2**Flammability** 0**Instability** 0**Physical and chemical properties** -**HMIS****Health hazards** 2**Flammability** 0**Physical hazards** 0**Personal protection** X**Key or legend to abbreviations and acronyms used in the safety data sheet****Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**

TWA	TWA (time-weighted average)	STEL	STEL (Short Term Exposure Limit)
Ceiling	Maximum limit value		

**Key literature references and sources for data used to compile the SDS**

Agency for Toxic Substances and Disease Registry (ATSDR)

U.S. Environmental Protection Agency ChemView Database

European Food Safety Authority (EFSA)

EPA (Environmental Protection Agency)

Acute Exposure Guideline Level(s) (AEGl(s))

U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act

U.S. Environmental Protection Agency High Production Volume Chemicals

Food Research Journal

Hazardous Substance Database

International Uniform Chemical Information Database (IUCLID)

Japan GHS Classification

Australia National Industrial Chemicals Notification and Assessment Scheme (NICNAS)

NIOSH (National Institute for Occupational Safety and Health)

National Library of Medicine's ChemID Plus (NLM CIP)

National Library of Medicine's PubMed database (NLM PUBMED)

National Toxicology Program (NTP)

New Zealand's Chemical Classification and Information Database (CCID)

Organization for Economic Co-operation and Development Environment, Health, and Safety Publications

Organization for Economic Co-operation and Development High Production Volume Chemicals Program

Organization for Economic Co-operation and Development Screening Information Data Set

World Health Organization

**Revision date**

20-October-2022

**Revision Note**

No information available.

**Disclaimer**

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

**End of Safety Data Sheet**



**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](mailto:qualityassurance@spectrumchemical.com)

Sincerely,

A handwritten signature in black ink, appearing to read "Oralia Chavez", written in a cursive style.

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        | • Parabens      |
| • Antibiotics       | • Pesticides    |
| • Bisphenol A (BPA) | • Phthalates    |
| • CMR Substances    | • Preservatives |



**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](mailto:TechServices@spectrumchemical.com).

Sincerely,

Technical Services  
Spectrum Chemical Mfg. Corp.

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

CORPORATE HEADQUARTERS

769 Jersey Avenue  
New Brunswick, NJ 08901  
PHONE 732.214.1300  
FAX 732.246.7132

WEST COAST FACILITY

14422 South San Pedro Street  
Gardena, California 90248  
PHONE 310.516.8000  
FAX 310.516.9843



**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](mailto:TechServices@spectrumchemical.com).

Sincerely,

Technical Services  
Spectrum Chemical Mfg. Corp.

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

CORPORATE HEADQUARTERS

769 Jersey Avenue

New Brunswick, NJ 08901

PHONE 732.214.1300

FAX 732.246.7132

WEST COAST FACILITY

14422 South San Pedro Street

Gardena, California 90248

PHONE 310.516.8000

FAX 310.516.9843

## 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.



**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](http://www.SpectrumChemical.com)

**C<sub>17</sub>H<sub>18</sub>F<sub>3</sub>NO•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](http://www.P65Warnings.ca.gov)

Repackaged by Spectrum as:  
**Lot No. XQ####**

B 9/111GHS-A      ?

### 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