



SAFETY DATA SHEET

1. Identification

Product identifier	Fluvoxamine Maleate	
Other means of identification		
Catalog number	1285909	
CAS number	61718-82-9	
Chemical name	1-Pentanone, 5-methoxy-1-[4-(trifluoromethyl)phenyl]-, O-(2-aminoethyl)oxime, (E)-, (Z)-2-butenedioate (1:1)	
Recommended use	For analytical laboratory use only.	
Recommended restrictions	Not for use as a drug. Not for administration to humans or animals.	
Manufacturer/Importer/Supplier/Distributor information		
Manufacturer		
Company name	U. S. Pharmacopeia	
Address	12601 Twinbrook Parkway Rockville MD 20852-1790 United States	
Telephone	Technical Services	301-816-8129
Website	www.usp.org	
E-mail	RSTECH@usp.org	
Emergency phone number	CHEMTREC within US & Canada	1-800-424-9300
	CHEMTREC outside US & Canada	+1 703-527-3887

2. Hazard(s) identification

Physical hazards	Not classified.	
Health hazards	Acute toxicity, oral	Category 4
	Acute toxicity, inhalation	Category 4
	Serious eye damage/eye irritation	Category 1
Environmental hazards	Not classified.	
OSHA defined hazards	Not classified.	
Label elements		



Signal word	Danger
Hazard statement	Harmful if swallowed. Harmful if inhaled. Causes serious eye damage.
Precautionary statement	
Prevention	Wash thoroughly after handling. Avoid breathing dust/fume. Wear eye protection/face protection. Use only outdoors or in a well-ventilated area.
Response	If swallowed: Call a poison center/doctor if you feel unwell. Rinse mouth. If inhaled: Remove person to fresh air and keep comfortable for breathing. Call a poison center/doctor 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. Immediately call a poison center/doctor.
Storage	Not available.
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.
Hazard(s) not otherwise classified (HNOC)	None known.

3. Composition/information on ingredients

Substance

Chemical name	Common name and synonyms	CAS number	%
Fluvoxamine Maleate		61718-82-9	100

Information provided in the SDS is not specific to the lot provided. Refer to the label and USP Certificate/Product Information Sheet for the assigned value of a particular lot.

4. First-aid measures

Inhalation	If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Call a physician if symptoms develop or persist. Do not use mouth-to-mouth method if the substance is inhaled. Induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device.
Skin contact	Rinse skin with water/shower. Get medical attention if irritation develops and persists.
Eye contact	Call a physician or poison control center immediately. Rinse with water. Remove contact lenses, if present and easy to do. Continue rinsing.
Ingestion	Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately. Do not induce vomiting without advice from poison control center. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs.
Most important symptoms/effects, acute and delayed	Pharmacologically active material. Occupational exposure may cause physiological effects. Serotonin syndrome.
Indication of immediate medical attention and special treatment needed	Provide general supportive measures and treat symptomatically.
General information	Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

5. Fire-fighting measures

Suitable extinguishing media	Water. Foam. Dry chemical or CO2. Use fire-extinguishing media appropriate for surrounding materials.
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	No unusual fire or explosion hazards noted.
Special protective equipment and precautions for firefighters	Wear suitable protective equipment.
Fire fighting equipment/instructions	Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.
Specific methods	Cool containers exposed to flames with water until well after the fire is out.
General fire hazards	No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Wear appropriate personal protective equipment. Ensure adequate ventilation. Avoid inhalation of dust from the spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. For personal protection, see section 8 of the SDS.
Methods and materials for containment and cleaning up	Clean surface thoroughly to remove residual contamination. Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid the generation of dusts during clean-up. For waste disposal, see section 13 of the SDS.
Environmental precautions	Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling

As a general rule, when handling USP materials, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential.

Conditions for safe storage, including any incompatibilities

Store in tight container. This material should be handled and stored per label instructions to ensure product integrity.

8. Exposure controls/personal protection

Occupational exposure limits

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

Exposure limit values

Industrial Use Material

	Type	Value
Fluvoxamine Maleate (CAS 61718-82-9)	TWA	120 micrograms/m3

Biological limit values

No biological exposure limits noted for the ingredient(s).

Appropriate engineering controls

For laboratory operations, use local exhaust ventilation or a ventilated enclosure for high energy operations such as particle sizing. Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred.

Individual protection measures, such as personal protective equipment

Eye/face protection

Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.

Skin protection

Hand protection

Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent.

Other

Train employees in proper gowning and degowning practices. Wear lab coat. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do not wear protective garments in common areas (e.g., cafeterias) or out-of-doors.

Respiratory protection

Respirators are generally not required for laboratory operations. Use a tight-fitting full-face respirator with HEPA filters for spill cleanup. Choose respiratory protection appropriate to the task and the level of existing engineering controls.

Thermal hazards

Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations

Handling practices in this SDS are recommendations for laboratory use of USP materials.

9. Physical and chemical properties

Appearance

Appearance descriptions are general information and not specific to any USP lot.

Physical state

Solid.

Form

Crystalline powder.

Color

White. Off-white.

Odor

Odorless. Practically odorless.

Odor threshold

Not available.

pH

Not available.

Melting point/freezing point

249.8 - 253.4 °F (121 - 123 °C)

Initial boiling point and boiling range

Not available.

Flash point

Not available.

Evaporation rate

Not available.

Flammability (solid, gas)

Not available.

Upper/lower flammability or explosive limits

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 Not available.

Relative density Not available.

Solubility(ies)

Solubility (water) Sparingly soluble.

Solubility (other) Chloroform: Freely soluble.
Ethanol: Freely soluble.
Ether: Practically insoluble.
Methanol: Freely soluble.

Auto-ignition temperature Not available.

Decomposition temperature Not available.

Viscosity Not available.

Other information

Chemical family Aralkylketone derivative.

Molecular formula C15H21F3N2O2 . C4H4O4

Molecular weight 434.41 g/mol

pH in aqueous solution 3.9 Solution 1%

10. Stability and reactivity

Reactivity The product is stable and non-reactive under normal conditions of use, storage and transport.

Chemical stability Material is stable under normal conditions.

Possibility of hazardous reactions No dangerous reaction known under conditions of normal use.

Conditions to avoid Contact with incompatible materials.

Incompatible materials None known.

Hazardous decomposition products F-. NOx. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

11. Toxicological information**Information on likely routes of exposure**

Inhalation Harmful if inhaled.

Skin contact Knowledge about health hazard is incomplete.

Eye contact Causes serious eye damage.

Ingestion Harmful if swallowed. Based on information from therapeutic use, this material may cause: Suicidal thoughts and behaviors. Serotonin syndrome.

Symptoms related to the physical, chemical and toxicological characteristics Selective serotonin reuptake inhibitors (SSRIs): Agitation. Nervousness. Confusion. Headache. Tiredness. Dizziness. Insomnia. Blurred vision. Tremor. Weakness. Motor restlessness. Body aches or pain. Dilated pupils. Fever. Sweating. Increased urination. Dry mouth. Gastrointestinal disturbances. Decreased or increased appetite. Skin rash. Decreased sexual ability or desire. Absence of menstrual period. Discharge of milk-like substance from the breast. Fast heart rate.

Information on toxicological effects

Acute toxicity Harmful if inhaled. Harmful if swallowed.

Product	Species	Test Results
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Fluvoxamine Maleate (CAS 61718-82-9)		
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<u>Acute</u>		
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Dermal		
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LD50	Rat	> 5000 mg/kg
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Product	Species	Test Results
Inhalation		
LC50	Rat	1.03 mg/l, 4 hr
Oral		
LD50	Mouse	1100 mg/kg
	Rat	1470 - 2000 mg/kg
Skin corrosion/irritation	Based on available data, the classification criteria are not met.	
Serious eye damage/eye irritation	Causes serious eye damage.	
Local effects		
Irritation test		
Result: Irritant.		
Species: Rabbit		
Organ: Eyes.		
Severity: Severe.		
Irritation test		
Result: Non-irritating.		
Species: Rabbit		
Organ: Skin.		
Respiratory or skin sensitization		
Respiratory sensitization	Knowledge about sensitization hazard is incomplete.	
Skin sensitization	Knowledge about sensitization hazard is incomplete.	
Germ cell mutagenicity	Knowledge about mutagenicity is incomplete.	
Mutagenicity		
Ames microbial mutagen test		
Result: Negative (with and without activation).		
In vitro chromosomal aberration test		
Result: Negative.		
Micronucleus test		
Result: Negative.		
Species: Mouse		
Carcinogenicity	Based on available data, the classification criteria are not met.	
135 - 240 mg/kg Carcinogenicity test		
Result: No evidence of carcinogenicity.		
Species: Hamster		
Test Duration: 26 months		
160 - 240 mg/kg Carcinogenicity test		
Result: No evidence of carcinogenicity.		
Species: Rat		
Test Duration: 30 months		
IARC Monographs. Overall Evaluation of Carcinogenicity		
Not listed.		
OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)		
Not listed.		
US. National Toxicology Program (NTP) Report on Carcinogens		
Not listed.		
Reproductive toxicity	Based on available data, the classification criteria are not met.	
	Therapeutic use of SSRIs late in pregnancy may be associated with a transient syndrome of central nervous system, motor, respiratory, and gastrointestinal effects in the newborn.	
Reproductivity		
> 120 mg/kg Reproductivity test		
Result: Developmental toxicity was observed.		
Species: Rat		
240 mg/kg Reproductivity test		
Result: Fertility was impaired.		
Species: Rat		
40 mg/kg Reproductivity test		
Result: No adverse effects on embryofetal development was observed.		
Species: Rat		

Reproductivity

60 mg/kg Reproductivity test

Result: No adverse fertility effects were seen.

Species: Rat

Specific target organ toxicity - single exposure Knowledge about health hazard is incomplete.

Specific target organ toxicity - repeated exposure Knowledge about health hazard is incomplete.

Aspiration hazard Based on available data, the classification criteria are not met.

Further information Pharmacologically active material. Occupational exposure may cause physiological effects.

12. Ecological information

Ecotoxicity

Product	Species	Test Results
Fluvoxamine Maleate (CAS 61718-82-9)		
Aquatic		
Algae	EC50	0.22 mg/l, 72 h
Crustacea	EC50	7.9 mg/l, 48 h
Acute		
Fish	LC50	6.4 mg/l, 96 h
Persistence and degradability	No data is available on the degradability of this product.	
Bioaccumulative potential	No data available.	
Mobility in soil	No data available.	
Other adverse effects	No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.	

13. Disposal considerations

Disposal instructions	Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste.
Local disposal regulations	Dispose in accordance with all applicable regulations.
Hazardous waste code	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
Waste from residues / unused products	Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
Contaminated packaging	Since emptied containers may retain product residue, follow label warnings even after container is emptied. Empty containers should be taken to an approved waste handling site for recycling or disposal.

14. Transport information

DOT

UN number	UN3077
UN proper shipping name	Environmentally hazardous substance, solid, n.o.s. (Fluvoxamine Maleate)
Transport hazard class(es)	
Class	9
Subsidiary risk	-
Packing group	III

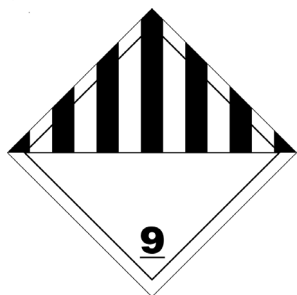
IATA

UN number	UN3077
UN proper shipping name	Environmentally hazardous substance, solid, n.o.s. (Fluvoxamine Maleate)
Transport hazard class(es)	
Class	9
Subsidiary risk	-
Packing group	III
Other information	
Passenger and cargo aircraft	Allowed with restrictions.
Cargo aircraft only	Allowed with restrictions.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable.

DOT; IATA



General information

It is the shipper's responsibility to determine the correct transport classification at the time of shipment.

15. Regulatory information

US federal regulations

CERCLA/SARA Hazardous Substances - Not applicable.

One or more components are not listed on TSCA.
This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

Toxic Substances Control Act (TSCA)

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical

Yes

Classified hazard categories

Acute toxicity (any route of exposure)
Serious eye damage or eye irritation

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA)

Not regulated.

US state regulations

California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins. For more information go to www.P65Warnings.ca.gov.

International Inventories

Country(s) or region

Australia

Inventory name

Australian Inventory of Chemical Substances (AICS)

On inventory (yes/no)*

No

Country(s) or region	Inventory name	On inventory (yes/no)*
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	Yes
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date	06-25-2004
Revision date	03-08-2022
Version #	05
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