



SAFETY DATA SHEET

1. Identification

Product identifier	Prozac®
Other means of identification	
Item Code	ZD0079, CK0857, MS8320, ND0845, ND0966, ND0967, ND1008, ND1014, ND1015, ND1024, ND1058, ND1060, ND1066, ND1107, ND1108, PU3004, PU3103, PU3104, PU3105, PU3106, PU3107, PU3109, PU3120, PU3160, PU3161, PU3210, PU3220, QA512G, SA1031, SA1032, SA1035, SA1036, TA4006, TA4007, TA4169, TA4171, TA4400, UC5014, UC5015, UC5016, UC5370, UC5371, UC5905, UC8957, UC8963, UC9526, UC9551, UC9552, UC9559, VF0144, VF0145, VF0156, VF0236, VF0237, VF0268, VF0269, VF0270, VF0293, VF0299, VF0318, VF0319, VF0324, VF0326, VF0330, VF0332, VF0334, VF0339, VF0359
Synonyms	Starter Kit Prozac (7-Pulvules and 7-Tablets) * Fluoxetine HCl * Fluoxetine Hydrochloride * Fluoxetine * Fluoxetine Hydrochloride Capsules * Fluoxetine Hydrochloride Tablets * Fluoxetine Hydrochloride Capsule Mix * Fluoxetine Hydrochloride Tablet Mix * 110140 Formulation * 3105 * Benzenepropanamine, N-methyl-gamma-[4-(trifluoromethyl)phenoxy]-, hydrochloride * (+)-N-Methyl-3-phenyl-3-[(alpha,alpha,alpha-trifluoro-p-tolyl)oxy]propylamine hydrochloride
Recommended use	Pharmaceutical
Recommended restrictions	None known.
Manufacturer/Importer/Supplier/Distributor information	
Manufacturer	
Company name	Eli Lilly and Company
Address	Lilly Corporate Center Indianapolis, IN 46285 United States
Telephone	Phone: +1-317-276-2000
E-mail	lilly_msds@lilly.com
Emergency phone number	CHEMTREC: +1-800-424-9300

2. Hazard(s) identification

Physical hazards	Not classified.	
Health hazards	Acute toxicity, inhalation	Category 4
	Skin corrosion/irritation	Category 2
	Serious eye damage/eye irritation	Category 1
	Specific target organ toxicity, single exposure	Category 3 narcotic effects
	Specific target organ toxicity, repeated exposure	Category 2
OSHA defined hazards	Not classified.	
Label elements		



Signal word	Danger
Hazard statement	
H315	Causes skin irritation.
H318	Causes serious eye damage.
H332	Harmful if inhaled.
H336	May cause drowsiness or dizziness.
H373	May cause damage to organs (Liver) through prolonged or repeated exposure.
Precautionary statement	
Prevention	

P280

Wear protective gloves/protective clothing/eye protection/face protection.

Response

P304 + P340

IF INHALED: Remove person to fresh air and keep comfortable for breathing.

P305 + P351 +
P338

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P310

Immediately call a POISON CENTER/doctor.

Storage

Not available.

Disposal

Not available.

Hazard(s) not otherwise classified (HNOC)

None known.

Supplemental information

None.

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
Fluoxetine Hydrochloride	(3S)-N-methyl-3-phenyl-3-[4-(trifluoromethyl)phenoxy]propan-1-amine hydrochloride	56296-78-7	4 - 20

Composition comments

Remaining components of this product are non-hazardous and/or are present at concentrations below reportable levels.

4. First-aid measures

Inhalation

Move to fresh air. Oxygen or artificial respiration if needed. 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.

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.

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).

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.

Environmental precautions Prevent further leakage or spillage if safe to do so.

7. Handling and storage

Precautions for safe handling Avoid contact with eyes, skin, and clothing. Wear personal protective equipment. See Section 8 of the SDS for Personal Protective Equipment.

Conditions for safe storage, including any incompatibilities Storage temperature: between 15 and 30 C (59 to 86 F).

8. Exposure controls/personal protection

Occupational exposure limits

Lilly (LEG)

Components

Type

Value

Fluoxetine Hydrochloride
(CAS 56296-78-7)

TWA (12hrs)

30 ug/m3

TWA (8hrs)

50 ug/m3

Biological limit values

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

Appropriate engineering controls

Intact capsules or tablets are not considered hazardous under normal handling procedures and protective equipment is not required. The recommendations in this section are intended for manufacturing or other situations where exposure to contents may occur.

Open handling is not recommended. Use appropriate control measures such as fume hood, ventilated enclosure, local exhaust ventilation, or down-draft booth.

Individual protection measures, such as personal protective equipment

Eye/face protection

Safety glasses with side shields recommended. If splash potential or dusty operations, wear goggles/faceshield.

Skin protection

Hand protection

Chemical resistant gloves.

Other

Chemical-resistant gloves and impermeable body covering to minimize skin contact.

Respiratory protection

If the applicable occupational exposure level (OEL) is anticipated to be exceeded, wear an approved respirator with sufficient protection factor to control exposure below the OEL.

Thermal hazards

Not available.

General hygiene considerations

Engineering controls should be used as the primary means to control workplace exposures. Follow good workplace hygiene practices such as washing hands after handling this material.

9. Physical and chemical properties

Appearance

White powder or pellets finished as capsules or coated tablets

Physical state

Solid.

Form

Capsules or Tablet.

Color

Not available.

Odor

Odorless

Odor threshold

Not available.

pH

Not available.

Melting point/freezing point

Not available.

Initial boiling point and boiling range

Not available.

Flash point

Not applicable.

Evaporation rate

Not available.

Flammability (solid, gas)

No test data 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	No data available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Soluble in water.
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.

10. Stability and reactivity

Reactivity	Not water reactive.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	Hazardous polymerization does not occur.
Conditions to avoid	None known.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	Hazardous decomposition products formed under fire conditions.

11. Toxicological information

Information on toxicological effects

Acute toxicity Harmful if inhaled.

Components	Species	Test Results
Fluoxetine Hydrochloride (CAS 56296-78-7)		
Acute		
Dermal		
LD50	Rabbit	> 500 mg/kg
Inhalation		
LC50	Rat	898 mg/m3, 1 h
Oral		
LD50	Monkey	> 50 mg/kg
	Mouse	248 mg/kg
	Rat	451 mg/kg

Skin corrosion/irritation Rabbit: No irritation. Skin irritation has been reported with occupational exposure. (Active ingredient)

Serious eye damage/eye irritation Rabbit: Corrosive. (Active ingredient)

Respiratory or skin sensitization

Respiratory sensitization Due to lack of data the classification is not possible.

Skin sensitization Due to lack of data the classification is not possible.

Germ cell mutagenicity Result in genetic toxicity assays (in vitro and in vivo): Negative (Active ingredient)
Based on available data, the classification criteria are not met.

Carcinogenicity Animal testing did not show any carcinogenic effects.
Based on available data, the classification criteria are not met. (Active ingredient)

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Reproductive toxicity

Two fertility studies conducted in adult rats indicated no adverse effects on fertility. In embryo-fetal development studies in rats and rabbits, there was no evidence of teratogenicity. However, in rat reproduction studies, an increase in stillborn pups, a decrease in pup weight, and an increase in pup deaths during the first 7 days postpartum occurred following maternal exposure to 7.5 mg/kg/day during gestation and lactation. There was no evidence of developmental neurotoxicity in the surviving offspring of rats. The no effect dose for rat pup mortality was 5 mg/kg/day.

Data on a large number of exposed pregnancies in humans indicate no appearance of adverse effects on pregnancy or on the overall health of the fetus/newborn child. However, a few epidemiological studies have noted that some women treated with fluoxetine and other SSRIs late in the third trimester have had newborns with increased complications that could be consistent with drug discontinuation syndrome (e.g. transient jitteriness, difficulty feeding, tachypnea and irritability) and required prolonged hospitalizations.

There are no adequate and well-controlled clinical studies on the use of fluoxetine in pregnant women. Results of a number of published epidemiological studies assessing the risk of fluoxetine exposure during the first trimester of pregnancy have demonstrated inconsistent results. More than 10 studies failed to demonstrate an increased risk for congenital malformations. An epidemiological study reported an increased risk of cardiovascular malformations in infants born to women exposed to fluoxetine during the first trimester of pregnancy compared to women who were not exposed to fluoxetine. However, a causal relationship has not been established. (Active ingredient)

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

Specific target organ toxicity - single exposure

May cause drowsiness or dizziness. (Active ingredient)

Specific target organ toxicity - repeated exposure

Liver effects (reversible increases in serum enzymes, slight hepatic fat deposition, tissue changes). (Active ingredient)

Aspiration hazard

No aspiration toxicity classification

Further information

In a juvenile toxicology study in rats, where the exposure period corresponds to human childhood and adolescence, administration of 30 mg/kg resulted in skeletal muscle necrosis. Other findings in rats included necrosis of the testis and immaturity and inactivity of the female reproductive tract. Following an approximate 11-week recovery period, sperm assessments indicated an approximately 30% decrease in sperm concentrations without affecting sperm morphology or motility. Microscopic evaluation indicated that testicular degeneration was irreversible. Delays in sexual maturation occurred with administration of 10 or 30 mg/kg. The significance of these findings in humans is unknown. Femur lengths at 30 mg/kg increased to a lesser extent compared with control rats. (Active ingredient)

12. Ecological information

Ecotoxicity

Very toxic to aquatic life with long lasting effects.

Components	Species	Test Results
Fluoxetine Hydrochloride (CAS 56296-78-7)		
Other	NOEC	Selenastrum capricornutum (new name Pseudokirchnerella subca) 1.2 µg/l
Acute	IC50	1000 mg/l Bacteria (Soil) 250 mg/l Blue-green algae 64 mg/l Bacteria (n-fixing) (Azotobacter chroococcum) 64 mg/l Mold 64 mg/l Fungus
Other	EC50	Selenastrum capricornutum (new name Pseudokirchnerella subca) 30.5 µg/l (average specific growth rate)
Aquatic		
Acute		
Crustacea	IC50	Daphnia magna 0.94 mg/l, 48 h
Fish	LC50	Rainbow Trout 1.57 mg/l, 96 h

Persistence and degradability

Fluoxetine Hydrochloride:
Hydrolysis rate (1/day): 0,0, 0 (pH 5, 7, 9)
Aerobic biodegradation half-life (days): not measurable

Bioaccumulative potential

log Kow: < 4. (Fluoxetine Hydrochloride)

Partition coefficient n-octanol / water (log Kow)

Fluoxetine Hydrochloride

0.93, (pH 5)

1.78, (pH 7)

2.63, (pH 9)

Mobility in soil No data available.**Other adverse effects** Not available.**Ecotoxicological Properties****Drinking Water****Components****Test Results**

Fluoxetine Hydrochloride

2.6 µg/l, (Lilly Aquatic Exposure Guideline)

Chronic Exposure of Aquatic Organisms**Components****Test Results**

Fluoxetine Hydrochloride

0.33 µg/l, (Lilly Aquatic Exposure Guideline)

Acute Exposure of Aquatic Organisms**Components****Test Results**

Fluoxetine Hydrochloride

2.1 µg/l, (Lilly Aquatic Exposure Guideline)

13. Disposal considerations**Disposal instructions** Dispose of contents/container in accordance with local/regional/national/international regulations.**14. Transport information****DOT**

Not regulated as dangerous goods.

IATA**UN number** UN3077**UN proper shipping name** Environmentally hazardous substance, solid, n.o.s. (Fluoxetine Hydrochloride)**Transport hazard class(es)****Class** 9**Subsidiary risk** -**Packing group** III**Environmental hazards** Yes**ERG Code** 9L**Special precautions for user** Not available.**Other information****Passenger and cargo aircraft** Allowed.**Cargo aircraft only** Allowed.**IMDG****UN number** UN3077**UN proper shipping name** ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Fluoxetine Hydrochloride)**Transport hazard class(es)****Class** 9**Subsidiary risk** -**Packing group** III**Environmental hazards****Marine pollutant** Yes**EmS** F-A, S-F**Special precautions for user** Not available.**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code** Not available.

IATA; IMDG



Marine pollutant



15. Regulatory information

US federal regulations

This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.
CERCLA/SARA Hazardous Substances - Not applicable.

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 1910.1001-1050)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories

Immediate Hazard - Yes
Delayed Hazard - Yes
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

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

US. California Controlled Substances. CA Department of Justice (California Health and Safety Code Section 11100)

Not listed.

US. Massachusetts RTK - Substance List

Not regulated.

US. New Jersey Worker and Community Right-to-Know Act

Not listed.

US. Pennsylvania Worker and Community Right-to-Know Law

Not listed.

US. Rhode Island RTK

Not regulated.

US. California Proposition 65

Not Listed.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
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** 02-17-2015**Revision date** 09-04-2015**Version #** 03**Lilly Lab Code** Health: 3
Fire: 1
Reactivity: 1**List of abbreviations**LEG: Lilly Exposure Guideline
TWA: Time Weighted Average**Disclaimer**

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS MATERIAL SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information contact:
Eli Lilly and Company
Hazard Communication
+1-317-651-9533

Revision Information

Ecological Information: Ecotox Property Data
GHS: Classification