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-trifluor o-p-tolyl)oxy]propylamine hydrochloride

LY Number LY110140

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

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.
H336 May cause drowsiness or dizziness.
H373 May cause damage to organs (Liver) through prolonged or repeated exposure.

Precautionary statement

Prevention

P264 Wash thoroughly after handling.

P280	Wear protective gloves/protective clothing/eye protection/face protection.
Response	
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. Causes skin irritation. 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 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 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 The formulated material is not expected to pose an inhalation hazard.

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. (Fluoxetine hydrochloride)
Serious eye damage/eye irritation	Rabbit: Corrosive. (Fluoxetine hydrochloride)
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 (Fluoxetine hydrochloride) Based on available data, the classification criteria are not met.
Carcinogenicity	Animal testing did not show any carcinogenic effects. (Fluoxetine hydrochloride) Based on available data, the classification criteria are not met.

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

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. (Fluoxetine hydrochloride)

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

Specific target organ toxicity - single exposure

May cause drowsiness or dizziness. (Fluoxetine hydrochloride)

Specific target organ toxicity - repeated exposure

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

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. (Fluoxetine hydrochloride)

12. Ecological information

Ecotoxicity

Very toxic to aquatic life with long lasting effects.

Components		Species	Test Results
Fluoxetine Hydrochloride (CAS 56296-78-7)			
	NOEC	Selenastrum capricornutum (new name Pseudokirchnerella subca	1.2 µg/l
Acute			
	EC50	Selenastrum capricornutum (new name Pseudokirchnerella subca	30.5 µg/l (average specific growth rate)
	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
Aquatic			
Acute			
Crustacea	IC50	Daphnia magna	0.94 mg/l, 48 h
Fish	LC50	Rainbow Trout	1.57 mg/l, 96 h

LILLY AQUATIC EXPOSURE GUIDELINES:

Fluoxetine Hydrochloride

Drinking water LAEG (at the point where surface water is taken for drinking water): 2.6 µg/l

Fluoxetine Hydrochloride

Acute LAEG (at the edge of the acute mixing zone):	2.1 µg/l
Chronic LAEG (at the edge of the chronic mixing zone):	0.33 µg/l

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.

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

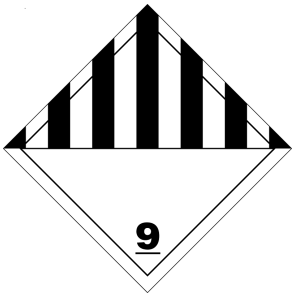
UN number	UN3077
UN proper shipping name	Environmentally hazardous substance, solid, n.o.s. (Fluoxetine Hydrochloride)
Transport hazard class(es)	
Class	9
Subsidiary risk	-
Packing group	III
Environmental hazards	Yes
ERG Code	9L
Special precautions for user	Not available.
Other information	
Passenger and cargo aircraft	Allowed with restrictions.
Cargo aircraft only	Allowed with restrictions.

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.

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)

Classified hazard categories
Skin corrosion or irritation
Serious eye damage or eye irritation
Specific target organ toxicity (single or repeated exposure)

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.

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 10-07-2019
Version # 12

List of abbreviations

ACGIH: American Conference of Governmental Industrial Hygienists.
DOT: Department of Transportation (49 CFR 172.101).
EC50: Effective Concentration 50%.
GHS: Globally Harmonized System of Classification and Labeling of Chemicals.
IATA: International Air Transport Association.
IC50: Inhibition Concentration 50%.
IMDG Code: International Maritime Dangerous Goods Code.
LD50: Lethal Dose 50%.
LEG: Lilly Exposure Guideline.
NOEC: No observed effect concentration.
NTP: National Toxicology Program.
OSHA: Occupational Safety & Health Administration.
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 SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANT ABILITY 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