Fluoxetine Hydrochloride

sc-207693

Material Safety Data Sheet

Hazard Alert Code Key:	EXTREME	HIGH	MODERATE	LOW

Section 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME
Fluoxetine Hydrochloride

STATEMENT OF HAZARDOUS NATURE
CONSIDERED A HAZARDOUS SUBSTANCE ACCORDING TO OSHA 29 CFR 1910.1200.

NFPA

SUPPLIER
Company: Santa Cruz Biotechnology, Inc.
Address:
2145 Delaware Ave
Santa Cruz, CA 95060
Telephone: 800.457.3801 or 831.457.3800
Emergency Tel: CHEMWATCH: From within the US and Canada: 877-715-9305
Emergency Tel: From outside the US and Canada: +800 2436 2255 (1-800-CHEMCALL) or call +613 9573 3112

PRODUCT USE
A antidepressant used in the treatment of endogenous depression. The antidepressant action is presumed to linked to the inhibition of central nervous system neuronal uptake of serotonin. WARNING: Fluoxetine may impair judgement, thinking or motor skills. Driving a vehicle or operating hazardous machinery should be avoided.

SYNONYMS
C17-H18-F3-N-O.HCl, C17-H18-F3-N-O.HCl, "N-methyl-3-phenyl-3-(p-trifluoromethylphenoxy)propylamine hydrochloride", "N-methyl-3-phenyl-3-(p-trifluoromethylphenoxy)propylamine hydrochloride", "N-methyl-3-phenyl-3-((alpha, alpha, alpha-trifluoro-p-", tolyl)oxy)propylamine, "N-methyl-3-phenyl-3-((alpha, alpha, alpha-trifluoro-p-", tolyl)oxy)propylamine, "3-(p-trifluoromethylphenoxy)-N-methyl-3-phenylpropylamine hydrochloride", "3-(p-trifluoromethylphenoxy)-N-methyl-3-phenylpropylamine hydrochloride", "(+/-)-N-methyl-gamma-(4-(trifluoromethyl)phenoxy)benzenepropanamine HCl", "(+/-)-N-methyl-gamma-(4-(trifluoromethyl)phenoxy)benzenepropanamine HCl", "aliphatic amine", Fontex, "Lilly 110140", Prozac, antidepressant

Section 2 - HAZARDS IDENTIFICATION

CANADIAN WHMIS SYMBOLS

EMERGENCY OVERVIEW

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RISK

Harmful if swallowed.
Irritating to skin.
Risk of serious damage to eyes.
Possible risk of harm to the unborn child.
Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

POTENTIAL HEALTH EFFECTS

ACUTE HEALTH EFFECTS

SWALLOWED

■ Accidental ingestion of the material may be harmful; animal experiments indicate that ingestion of less than 150 gram may be fatal or may produce serious damage to the health of the individual.
■ Serotonin syndrome (serious changes to how the brain, muscles and digestive system works due to high levels of serotonin in the body) may occur in therapy. Signs and symptoms of serotonin syndrome include

- restlessness
- fast heart beat
- fast changes in blood pressure
- diarrhoea and vomiting
- nausea
- hallucinations
- increased body temperature
- coma
- loss of coordination
- overactive reflexes

General side effects of serotonin reuptake inhibitors (SSRIs) are mostly present during the first 1-4 weeks while the body adapts to the drug (with the exception of sexual side effects, which tend to occur later in treatment). In fact, it often takes 6-8 weeks for the drug to begin reaching its full potential (the slow onset is considered a downside to treatment with SSRIs). Almost all SSRIs are known to cause one or more of these symptoms:

- anhedonia (inability to experience pleasure from normally pleasurable life events such as eating, exercise, and social or sexual interaction.)
- nausea
- drowsiness or somnolence
- headache
- clenching of teeth
- extremely vivid and strange dreams
- dizziness
- changes in appetite
- weight loss/gain (measured by a change in bodyweight of 7 pounds)
- may result in a double risk of bone fractures and injuries
- changes in sexual behaviour
- increased feelings of depression and anxiety (which may sometimes provoke panic attacks)
- tremors
- autonomic dysfunction including orthostatic tension, increased or reduced sweating
- akathisia (a syndrome characterised by unpleasant sensations of "inner" restlessness that manifests itself with an inability to sit still or remain motionless)
- liver or renal impairment
- thoughts of suicide
- Photosensitivity (increased risk of sunburn) (Use protective clothing, such as long sleeves and hats, and sunscreen to decrease the risk of sunburn.)

Common gastrointestinal side effects include nausea, vomiting, and diarrhoea, which are brought about by the actions of serotonin on the gastrointestinal tract.
Most side effects usually disappear after the adaptation phase, when the antidepressive effects begin to show. However, despite being called general, the side effects and their durations are highly individual and drug-specific. Usually the treatment is begun with a small dose to see how the patient's body reacts to the drug, after that either the dose can be adjusted
Mania or hypomania is a possible side-effect. Users with some type of bipolar disorder are at a much higher risk, however SSRI-induced mania in patients previously diagnosed with unipolar depression can trigger a bipolar diagnosis.
Sexual dysfunction: SSRIs can cause various types of sexual such as anorgasmia, erectile dysfunction, and diminished libido. Initial studies found that such side effects occur in less than 10% of patients, but since these studies relied on unprompted reporting, the frequency was

probably underestimated. In more recent studies, doctors have specifically asked about sexual difficulties, and found that they are present in between 17% and 41% of patients. This dysfunction occasionally disappears spontaneously without stopping the SSRI, and in most cases resolves after discontinuation. In some cases, however, it does not; this is known as Post SSRI Sexual Dysfunction (PSSD).
It is believed that sexual dysfunction is caused by an SSRI induced reduction in dopamine. Stimulation of postsynaptic 5-HT2 and 5-HT3 receptors decreases dopamine release from the Substantia nigra.
Cardiovascular side effects are very rare with SSRI use, with a reported incidence of less than 0.0003 percent. SSRIs inhibit cardiac and vascular sodium, calcium and potassium channels and prolong QT intervals. However, a number of large studies of patients without known pre-existing heart disease have reported no EKG changes related to SSRI use. In overdose, fluoxetine has been reported to cause sinus tachycardia, myocardial infarction, junctional rhythms and trigeminy. Some authors have suggested electrocardiographic monitoring in patients with severe pre-existing cardiovascular disease who are taking SSRI's.
Discontinuation syndrome: SSRIs are addictive as discontinuing their use is known to produce both somatic and psychological withdrawal symptoms.
Suicidality and aggression: Similarly to other antidepressants, SSRIs can cause suicidality in children. A 2004 Food and Drug Administration (FDA) analysis of clinical trials on children with major depressive disorder found statistically significant increases of the risks of "possible suicidal ideation and suicidal behavior" by about 80%, and of agitation and hostility by about 130%. An additional analysis by the FDA also indicated 1.5-fold increase of suicidality in the 18–24 age group. This resulted in a black box warning on SSRI and other antidepressant medications regarding the increased risk of suicidality in patients younger than 24. In 2004, the Medicines and Healthcare products Regulatory Agency (MHRA) in the United Kingdom judged fluoxetine (Prozac) to be the only antidepressant that offered a favorable risk-benefit ratio in children with depression, though it was also associated with a slight increase in the risk of self-harm and suicidal ideation. Only two SSRIs are licensed for use with children in the UK, sertraline (Zoloft) and fluvoxamine (Luvox), and only for the treatment of obsessive-compulsive disorder. Fluoxetine, despite having a favorable risk-benefit ratio for use with depression in adolescents and children, is not licensed for this use.
Other studies on SSRIs and suicide among adolescents are equivocal; rates of suicide attempts in high-risk populations appear to be unaffected by SSRI prescriptions in adults. There is also evidence that higher rates of SSRI prescriptions are associated with lower rates of suicide in children, though since the evidence is correlational, the true nature of the relationship is unclear. The introduction of a warning regarding the association between SSRIs and suicide led to a decrease in prescriptions for the medications in 2003 and 2004, and these decreases in prescriptions were associated with an increase in actual number of teenage suicide.
Interaction with carbohydrate metabolism: Serotonin is also involved in regulation of carbohydrate metabolism. Few analyses of the role of SSRIs in treating depression cover the effects on carbohydrate metabolism from intervening in serotonin handling by the body.
Pregnancy: When taken by pregnant women, selective serotonin reuptake inhibitors (SSRIs) cross the placenta and have the potential to affect newborns. Sertraline and paroxetine have been associated with congenital malformations. Some evidence suggests that SSRIs are associated with neonatal complications such as neonatal abstinence syndrome (NAS) and persistent pulmonary hypertension (PPHN).
Neonatal abstinence syndrome is a withdrawal syndrome in newborn babies which has been documented in SSRI treatment.
Persistent pulmonary hypertension (PPHN) is a serious and life-threatening, but rare, lung condition that occurs soon after birth of the newborn. Newborn babies with PPHN have high pressure in their lung blood vessels and are not able to get enough oxygen into their bloodstream. About 1 to 2 babies per 1000 babies born in the U.S. develop PPHN shortly after birth, and often they need intensive medical care. One study has found that PPHN is six times more common in babies whose mothers take an SSRI antidepressant after the 20th week of the pregnancy compared to babies whose mothers do not take an antidepressant.[.

EYE

■ If applied to the eyes, this material causes severe eye damage.

SKIN

■ This material can cause inflammation of the skin oncontact in some persons.
■ The material may accentuate any pre-existing dermatitis condition.
■ This material is a photosensitizer. Certain individuals working with this substance may show allergic reaction of the skin under sunlight. This results in sensitivity to sunburn (may be severe) unless protective covering and 15+PF sunscreen are used. Responses may vary from sunburn-like effects to swelling and blistering lesions.
■ Open cuts, abraded or irritated skin should not be exposed to this material.
■ Entry into the blood-stream, through, for example, cuts, abrasions or lesions, may produce systemic injury with harmful effects. Examine the skin prior to the use of the material and ensure that any external damage is suitably protected.

INHALED

■ The material is not thought to produce respiratory irritation (as classified using animal models). Nevertheless inhalation of dusts, or fume, especially for prolonged periods, may produce respiratory discomfort and occasionally, distress.
■ Inhalation of dusts, generated by the material during the course of normal handling, may be damaging to the health of the individual.
■ Persons with impaired respiratory function, airway diseases and conditions such as emphysema or chronic bronchitis, may incur further disability if excessive concentrations of particulate are inhaled.

CHRONIC HEALTH EFFECTS

■ Long-term exposure to the product is not thought to produce chronic effects adverse to the health (as classified using animal models); nevertheless exposure by all routes should be minimized as a matter of course.
Results in experiments suggest that this material may cause disorders in the development of the embryo or fetus, even when no signs of poisoning show in the mother.
Long term exposure to high dust concentrations may cause changes in lung function i.e. pneumoconiosis; caused by particles less than 0.5

micron penetrating and remaining in the lung. Prime symptom is breathlessness; lung shadows show on X-ray.

Section 3 - COMPOSITION / INFORMATION ON INGREDIENTS

HAZARD RATINGS

		Min	Max
Flammability:	1		
Toxicity:	2		
Body Contact:	3		
Reactivity:	1		
Chronic:	2		

Min/Nil=0
Low=1
Moderate=2
High=3
Extreme=4

NAME	CAS RN	%
fluoxetine hydrochloride	56296-78-7	>98

Section 4 - FIRST AID MEASURES

SWALLOWED

■

- IF SWALLOWED, REFER FOR MEDICAL ATTENTION, WHERE POSSIBLE, WITHOUT DELAY.
- Where Medical attention is not immediately available or where the patient is more than 15 minutes from a hospital or unless instructed otherwise:
- For advice, contact a Poisons Information Center or a doctor.
- Urgent hospital treatment is likely to be needed.
- If conscious, give water to drink.
- INDUCE vomiting with fingers down the back of the throat, ONLY IF CONSCIOUS. Lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration.

NOTE: Wear a protective glove when inducing vomiting by mechanical means.

- In the mean time, qualified first-aid personnel should treat the patient following observation and employing supportive measures as indicated by the patient's condition.
- If the services of a medical officer or medical doctor are readily available, the patient should be placed in his/her care and a copy of the MSDS should be provided. Further action will be the responsibility of the medical specialist.
- If medical attention is not available on the worksite or surroundings send the patient to a hospital together with a copy of the MSDS.

EYE

■ If this product comes in contact with the eyes:

- Immediately hold eyelids apart and flush the eye continuously with running water.
- Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids.
- Continue flushing until advised to stop by the Poisons Information Center or a doctor, or for at least 15 minutes.
- Transport to hospital or doctor without delay.
- Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.

SKIN

■ If skin contact occurs:

- Immediately remove all contaminated clothing, including footwear
- Flush skin and hair with running water (and soap if available).
- Seek medical attention in event of irritation.

INHALED

■

- If fumes or combustion products are inhaled remove from contaminated area.
- Lay patient down. Keep warm and rested.
- Prostheses such as false teeth, which may block airway, should be removed, where possible, prior to initiating first aid procedures.
- Apply artificial respiration if not breathing, preferably with a demand valve resuscitator, bag-valve mask device, or pocket mask as trained.

Perform CPR if necessary.
- Transport to hospital, or doctor.

NOTES TO PHYSICIAN

■ Treat symptomatically.

For selective serotonin reuptake inhibitors (SSRIs):

Serotonin toxicity is more pronounced following supra-therapeutic doses and overdoses, and they merge in a continuum with the toxic effects of overdose. The serotonergic toxicity of SSRIs increases with dose, but even in over-dose it is insufficient to cause fatalities from serotonin syndrome in healthy adults. The syndrome occurs in approximately 14 to 16 percent of persons who overdose on SSRIs.

It is usually only when drugs with different mechanisms of action are mixed together that elevations of central nervous system serotonin reach potentially fatal levels.

The symptoms are often described as a clinical triad of abnormalities:

- Cognitive effects: mental confusion, hypomania, hallucinations, agitation, headache, coma.
- Autonomic effects: shivering, sweating, fever, hypertension, tachycardia, nausea, diarrhea.
- Somatic effects: myoclonus/clonus (muscle twitching), hyperreflexia, tremor.

Symptom onset is usually rapid, often occurring within minutes after self-poisoning or a change in medication. Serotonin syndrome encompasses a wide range of clinical findings. Mild symptoms may only consist of tachycardia, shivering, diaphoresis (sweating), mydriasis (dilated pupils), myoclonus (intermittent tremor or twitching), as well as overactive or over-responsive reflexes. Moderate intoxication includes additional abnormalities such as hyperactive bowel sounds, hypertension and hyperthermia; a temperature as high as 40 C (104 F) is common in moderate intoxication. The overactive reflexes and clonus in moderate cases may be greater in the lower limbs than in the upper limbs. Mental status changes include hyper-vigilance and agitation. Severe symptoms include severe hypertension and tachycardia that may lead to shock. Severe cases often have agitated delirium as well as muscular rigidity and high muscular tension. Temperature may rise to above 41.1 C (106.0 F) in life-threatening cases. Other abnormalities include metabolic acidosis, rhabdomyolysis, seizures, renal failure, and disseminated intravascular coagulation, these effects usually arise as a consequence of hyperthermia.

SSRIs appear to be safer in overdose when compared with traditional antidepressants such as the tricyclic antidepressants. This relative safety is supported both by case series and studies of deaths per numbers of prescriptions. However, case reports of SSRI poisoning have indicated that severe toxicity can occur and deaths have been reported following massive single ingestions, although this is exceedingly uncommon when compared to the tricyclic antidepressants.

Because of the wide therapeutic index of the SSRIs, most patients will have mild or no symptoms following moderate overdoses. The most commonly reported severe effect following SSRI overdose is serotonin syndrome; serotonin toxicity is usually associated with very high overdoses or multiple drug ingestion. Other reported significant effects include coma, seizures, and cardiac toxicity.

Treatment for SSRI overdose is mainly based on symptomatic and supportive care. Medical care may be required for agitation, maintenance of the airways, and treatment for serotonin syndrome. ECG monitoring is usually indicated to detect any cardiac abnormalities.

Supportive care includes:

- the control of agitation,
- the administration of serotonin antagonists (cyproheptadine or methysergide),
- the control of autonomic instability, and the control of hyperthermia.

The intensity of therapy depends on the severity of symptoms.

If the symptoms are mild, treatment may only consist of:

- discontinuation of the offending medication or medications,
- offering supportive measures,
- giving benzodiazepines for myoclonus, and waiting for the symptoms to resolve.

Moderate cases should have:

- all thermal and cardiorespiratory abnormalities corrected and
- can benefit from serotonin antagonists such as cyproheptadine.

Critically ill patients should receive the above therapies as well as:

- sedation, neuromuscular paralysis, and
- intubation with artificial ventilation.

Upon initiation of therapy and the discontinuation of serotonergic drugs most cases of serotonin syndrome resolve within 24 hours.although delirium may persist for a number of days. Cases have reported muscle pain and weakness persisting for months although antidepressant withdrawal may contribute to ongoing features. Following appropriate medical management, serotonin syndrome is generally associated with a favorable prognosis.

Extensively metabolised in the liver to norfluoxetine and other metabolites. Norfluoxetine (the demethylation product) is also active in the blocking of serotonin uptake. An elimination half-life of 2-3 days for fluoxetine and 7-9 days for norfluoxetine has been reported.

In fluoxetine overdose:

Establish and maintain an airway: insure adequate oxygenation and ventilation. Activated charcoal which may be used with sorbitol, may be as or more effective than emesis or lavage.

Cardiac and general signs monitoring is recommended along with general symptomatic and supportive measures. Based on experience in animals which may not be relevant in humans, fluoxetine-induced seizures which fail to remit spontaneously may respond to diazepam. There is no specific antidote. Due the large volume of distribution of fluoxetine, forced diuresis, dialysis, haemoperfusion and exchange transfusion are unlikely to be of benefit.

Hazard Alert Code Key:	EXTREME	HIGH	MODERATE	LOW

Prescription Products Guide: 21st Edition.

Section 5 - FIRE FIGHTING MEASURES

Vapour Pressure (mmHG):	Negligible
Upper Explosive Limit (%):	Not available
Specific Gravity (water=1):	Not available
Lower Explosive Limit (%):	Not available

EXTINGUISHING MEDIA

- Water spray or fog.
- Foam.
- Dry chemical powder.
- BCF (where regulations permit).
- Carbon dioxide.

FIRE FIGHTING

- Alert Emergency Responders and tell them location and nature of hazard.
- Wear full body protective clothing with breathing apparatus.
- Prevent, by any means available, spillage from entering drains or water course.
- Use fire fighting procedures suitable for surrounding area.
- DO NOT approach containers suspected to be hot.
- Cool fire exposed containers with water spray from a protected location.
- If safe to do so, remove containers from path of fire.
- Equipment should be thoroughly decontaminated after use.

GENERAL FIRE HAZARDS/HAZARDOUS COMBUSTIBLE PRODUCTS

- Combustible solid which burns but propagates flame with difficulty.
- Avoid generating dust, particularly clouds of dust in a confined or unventilated space as dusts may form an explosive mixture with air, and any source of ignition, i.e. flame or spark, will cause fire or explosion. Dust clouds generated by the fine grinding of the solid are a particular hazard; accumulations of fine dust may burn rapidly and fiercely if ignited.
- Dry dust can be charged electrostatically by turbulence, pneumatic transport, pouring, in exhaust ducts and during transport.
- Build-up of electrostatic charge may be prevented by bonding and grounding.
- Powder handling equipment such as dust collectors, dryers and mills may require additional protection measures such as explosion venting.

Combustion products include: carbon monoxide (CO), carbon dioxide (CO_2), hydrogen chloride, phosgene, hydrogen fluoride, nitrogen oxides (NOx), other pyrolysis products typical of burning organic material.
May emit poisonous fumes.

FIRE INCOMPATIBILITY

■ Avoid contamination with oxidizing agents i.e. nitrates, oxidizing acids,chlorine bleaches, pool chlorine etc. as ignition may result.

PERSONAL PROTECTION

Glasses:
Gloves:
Respirator:
Particulate

Section 6 - ACCIDENTAL RELEASE MEASURES

MINOR SPILLS

- Clean up waste regularly and abnormal spills immediately.
- Avoid breathing dust and contact with skin and eyes.
- Wear protective clothing, gloves, safety glasses and dust respirator.

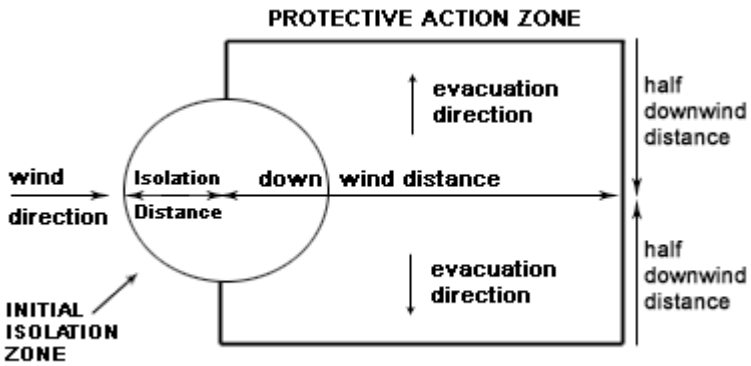
Hazard Alert Code Key:	EXTREME	HIGH	MODERATE	LOW

- Use dry clean up procedures and avoid generating dust.
- Vacuum up or sweep up. NOTE: Vacuum cleaner must be fitted with an exhaust micro filter (HEPA type) (consider explosion-proof machines designed to be grounded during storage and use).
- Dampen with water to prevent dusting before sweeping.
- Place in suitable containers for disposal.

MAJOR SPILLS

- Clear area of personnel and move upwind.
- Alert Emergency Responders and tell them location and nature of hazard.
- Wear full body protective clothing with breathing apparatus.
- Prevent, by any means available, spillage from entering drains or water course.
- Stop leak if safe to do so.
- Contain spill with sand, earth or vermiculite.
- Collect recoverable product into labeled containers for recycling.
- Neutralize/decontaminate residue.
- Collect solid residues and seal in labeled drums for disposal.
- Wash area and prevent runoff into drains.
- After clean up operations, decontaminate and launder all protective clothing and equipment before storing and re-using.
- If contamination of drains or waterways occurs, advise emergency services.

PROTECTIVE ACTIONS FOR SPILL



From IERG (Canada/Australia)	
Isolation Distance	25 meters
Downwind Protection Distance	250 meters

FOOTNOTES

1 PROTECTIVE ACTION ZONE is defined as the area in which people are at risk of harmful exposure. This zone assumes that random changes in wind direction confines the vapour plume to an area within 30 degrees on either side of the predominant wind direction, resulting in a crosswind protective action distance equal to the downwind protective action distance.
2 PROTECTIVE ACTIONS should be initiated to the extent possible, beginning with those closest to the spill and working away from the site in the downwind direction. Within the protective action zone a level of vapour concentration may exist resulting in nearly all unprotected persons becoming incapacitated and unable to take protective action and/or incurring serious or irreversible health effects.
3 INITIAL ISOLATION ZONE is determined as an area, including upwind of the incident, within which a high probability of localised wind reversal may expose nearly all persons without appropriate protection to life-threatening concentrations of the material.
4 SMALL SPILLS involve a leaking package of 200 litres (55 US gallons) or less, such as a drum (jerrican or box with inner containers). Larger packages leaking less than 200 litres and compressed gas leaking from a small cylinder are also considered "small spills". LARGE SPILLS involve many small leaking packages or a leaking package of greater than 200 litres, such as a cargo tank, portable tank or a "one-tonne" compressed gas cylinder.
5 Guide 151 is taken from the US DOT emergency response guide book.
6 IERG information is derived from CANUTEC - Transport Canada.

ACUTE EXPOSURE GUIDELINE LEVELS (AEGL) (in ppm)

AEGL 1: The airborne concentration of a substance above which it is predicted that the general population, including susceptible individuals, could experience notable discomfort, irritation, or certain asymptomatic nonsensory effects. However, the effects are not disabling and are transient and reversible upon cessation of exposure.
AEGL 2: The airborne concentration of a substance above which it is predicted that the general population, including susceptible individuals, could

experience irreversible or other serious, long-lasting adverse health effects or an impaired ability to escape.
AEGL 3: The airborne concentration of a substance above which it is predicted that the general population, including susceptible individuals, could experience life-threatening health effects or death.

Section 7 - HANDLING AND STORAGE

PROCEDURE FOR HANDLING

■

- Avoid all personal contact, including inhalation.
- Wear protective clothing when risk of exposure occurs.
- Use in a well-ventilated area.
- Prevent concentration in hollows and sumps.
- DO NOT enter confined spaces until atmosphere has been checked.
- DO NOT allow material to contact humans, exposed food or food utensils.
- Avoid contact with incompatible materials.
- When handling, DO NOT eat, drink or smoke.
- Keep containers securely sealed when not in use.
- Avoid physical damage to containers.
- Always wash hands with soap and water after handling.
- Work clothes should be laundered separately.
- Launder contaminated clothing before re-use.
- Use good occupational work practice.
- Observe manufacturer's storing and handling recommendations.
- Atmosphere should be regularly checked against established exposure standards to ensure safe working conditions are maintained.

Empty containers may contain residual dust which has the potential to accumulate following settling. Such dusts may explode in the presence of an appropriate ignition source.

- Do NOT cut, drill, grind or weld such containers.
- In addition ensure such activity is not performed near full, partially empty or empty containers without appropriate workplace safety authorisation or permit.

RECOMMENDED STORAGE METHODS

■ Glass container.

- Lined metal can, Lined metal pail/drum
- Plastic pail
- Polyliner drum
- Packing as recommended by manufacturer.
- Check all containers are clearly labeled and free from leaks.

For low viscosity materials

- Drums and jerricans must be of the non-removable head type.
- Where a can is to be used as an inner package, the can must have a screwed enclosure.

For materials with a viscosity of at least 2680 cSt. (23 deg. C) and solids (between 15 C deg. and 40 deg C.):

- Removable head packaging;
- Cans with friction closures and
- low pressure tubes and cartridges may be used.

- Where combination packages are used, and the inner packages are of glass, there must be sufficient inert cushioning material in contact with inner and outer packages * . - In addition, where inner packagings are glass and contain liquids of packing group I and II there must be sufficient inert absorbent to absorb any spillage *. - * unless the outer packaging is a close fitting molded plastic box and the substances are not incompatible with the plastic.

STORAGE REQUIREMENTS

■

- Store in original containers.
- Keep containers securely sealed.
- Store in a cool, dry, well-ventilated area.
- Store away from incompatible materials and foodstuff containers.
- Protect containers against physical damage and check regularly for leaks.

Hazard Alert Code Key:	EXTREME	HIGH	MODERATE	LOW

- Observe manufacturer's storing and handling recommendations.

SAFE STORAGE WITH OTHER CLASSIFIED CHEMICALS

+	X	+	X	X	+

X: Must not be stored together
O: May be stored together with specific preventions
+: May be stored together

Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

EXPOSURE CONTROLS

The following materials had no OELs on our records

• fluoxetine hydrochloride: CAS:56296-78-7 CAS:59333-67-4

MATERIAL DATA

FLUOXETINE HYDROCHLORIDE:

■ It is the goal of the ACGIH (and other Agencies) to recommend TLVs (or their equivalent) for all substances for which there is evidence of health effects at airborne concentrations encountered in the workplace.

At this time no TLV has been established, even though this material may produce adverse health effects (as evidenced in animal experiments or clinical experience). Airborne concentrations must be maintained as low as is practically possible and occupational exposure must be kept to a minimum.

NOTE: The ACGIH occupational exposure standard for Particles Not Otherwise Specified (P.N.O.S) does NOT apply.

Sensory irritants are chemicals that produce temporary and undesirable side-effects on the eyes, nose or throat. Historically occupational exposure standards for these irritants have been based on observation of workers' responses to various airborne concentrations. Present day expectations require that nearly every individual should be protected against even minor sensory irritation and exposure standards are established using uncertainty factors or safety factors of 5 to 10 or more. On occasion animal no-observable-effect-levels (NOEL) are used to determine these limits where human results are unavailable. An additional approach, typically used by the TLV committee (USA) in determining respiratory standards for this group of chemicals, has been to assign ceiling values (TLV C) to rapidly acting irritants and to assign short-term exposure limits (TLV STELs) when the weight of evidence from irritation, bioaccumulation and other endpoints combine to warrant such a limit. In contrast the MAK Commission (Germany) uses a five-category system based on intensive odour, local irritation, and elimination half-life. However this system is being replaced to be consistent with the European Union (EU) Scientific Committee for Occupational Exposure Limits (SCOEL); this is more closely allied to that of the USA.

OSHA (USA) concluded that exposure to sensory irritants can:

- cause inflammation
- cause increased susceptibility to other irritants and infectious agents
- lead to permanent injury or dysfunction
- permit greater absorption of hazardous substances and
- acclimate the worker to the irritant warning properties of these substances thus increasing the risk of overexposure.

Airborne particulate or vapor must be kept to levels as low as is practicably achievable given access to modern engineering controls and monitoring hardware. Biologically active compounds may produce idiosyncratic effects which are entirely unpredictable on the basis of literature searches and prior clinical experience (both recent and past).

PERSONAL PROTECTION

Hazard Alert Code Key:	EXTREME	HIGH	MODERATE	LOW

Consult your EHS staff for recommendations

EYE

■ For laboratory, larger scale or bulk handling or where regular exposure in an occupational setting occurs:

- Chemical goggles
- Face shield. Full face shield may be required for supplementary but never for primary protection of eyes
- Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lens or restrictions on use, should be created for each workplace or task. This should include a review of lens absorption and adsorption for the class of chemicals in use and an account of injury experience. Medical and first-aid personnel should be trained in their removal and suitable equipment should be readily available. In the event of chemical exposure, begin eye irrigation immediately and remove contact lens as soon as practicable. Lens should be removed at the first signs of eye redness or irritation - lens should be removed in a clean environment only after workers have washed hands thoroughly. [CDC NIOSH Current Intelligence Bulletin 59].

HANDS/FEET

■ Suitability and durability of glove type is dependent on usage. Important factors in the selection of gloves include: such as:

- frequency and duration of contact,
- chemical resistance of glove material,
- glove thickness and
- dexterity

Select gloves tested to a relevant standard (e.g. Europe EN 374, US F739).

- When prolonged or frequently repeated contact may occur, a glove with a protection class of 5 or higher (breakthrough time greater than 240 minutes according to EN 374) is recommended.
- When only brief contact is expected, a glove with a protection class of 3 or higher (breakthrough time greater than 60 minutes according to EN 374) is recommended.
- Contaminated gloves should be replaced.

Gloves must only be worn on clean hands. After using gloves, hands should be washed and dried thoroughly. Application of a non-perfumed moisturiser is recommended.

- Rubber gloves (nitrile or low-protein, powder-free latex). Employees allergic to latex gloves should use nitrile gloves in preference.
- Double gloving should be considered.
- PVC gloves.
- Protective shoe covers.
- Head covering.

OTHER

■

- For quantities up to 500 grams a laboratory coat may be suitable.
- For quantities up to 1 kilogram a disposable laboratory coat or coverall of low permeability is recommended. Coveralls should be buttoned at collar and cuffs.
- For quantities over 1 kilogram and manufacturing operations, wear disposable coverall of low permeability and disposable shoe covers.
- For manufacturing operations, air-supplied full body suits may be required for the provision of advanced respiratory protection.
- Eye wash unit.
- Ensure there is ready access to an emergency shower.
- For Emergencies: Vinyl suit

■

- Respirators may be necessary when engineering and administrative controls do not adequately prevent exposures.
- The decision to use respiratory protection should be based on professional judgment that takes into account toxicity information, exposure measurement data, and frequency and likelihood of the worker's exposure - ensure users are not subject to high thermal loads which may result in heat stress or distress due to personal protective equipment (powered, positive flow, full face apparatus may be an option).
- Published occupational exposure limits, where they exist, will assist in determining the adequacy of the selected respiratory . These may be government mandated or vendor recommended.
- Certified respirators will be useful for protecting workers from inhalation of particulates when properly selected and fit tested as part of a complete respiratory protection program.
- Use approved positive flow mask if significant quantities of dust becomes airborne.
- Try to avoid creating dust conditions.

RESPIRATOR

■

Protection Factor	Half-Face Respirator	Full-Face Respirator	Powered Air Respirator
10 x PEL	P1	-	PAPR-P1
	Air-line*	-	-

Hazard Alert Code Key:	EXTREME	HIGH	MODERATE	LOW
50 x PEL	Air-line**	P2	PAPR-P2	
100 x PEL	-	P3	-	
		Air-line*	-	
100+ x PEL	-	Air-line**	PAPR-P3	

* - Negative pressure demand ** - Continuous flow
Explanation of Respirator Codes:
Class 1 low to medium absorption capacity filters.
Class 2 medium absorption capacity filters.
Class 3 high absorption capacity filters.
PAPR Powered Air Purifying Respirator (positive pressure) cartridge.
Type A for use against certain organic gases and vapors.
Type AX for use against low boiling point organic compounds (less than 65ºC).
Type B for use against certain inorganic gases and other acid gases and vapors.
Type E for use against sulfur dioxide and other acid gases and vapors.
Type K for use against ammonia and organic ammonia derivatives
Class P1 intended for use against mechanically generated particulates of sizes most commonly encountered in industry, e.g. asbestos, silica.
Class P2 intended for use against both mechanically and thermally generated particulates, e.g. metal fume.
Class P3 intended for use against all particulates containing highly toxic materials, e.g. beryllium.
The local concentration of material, quantity and conditions of use determine the type of personal protective equipment required.
Use appropriate NIOSH-certified respirator based on informed professional judgement. In conditions where no reasonable estimate of exposure can be made, assume the exposure is in a concentration IDLH and use NIOSH-certified full face pressure demand SCBA with a minimum service life of 30 minutes, or a combination full facepiece pressure demand SAR with auxiliary self-contained air supply. Respirators provided only for escape from IDLH atmospheres shall be NIOSH-certified for escape from the atmosphere in which they will be used.

ENGINEERING CONTROLS

■ Enclosed local exhaust ventilation is required at points of dust, fume or vapor generation.
HEPA terminated local exhaust ventilation should be considered at point of generation of dust, fumes or vapors.
Barrier protection or laminar flow cabinets should be considered for laboratory scale handling.
The need for respiratory protection should also be assessed where incidental or accidental exposure is anticipated: Dependent on levels of contamination, PAPR, full face air purifying devices with P2 or P3 filters or air supplied respirators should be evaluated.
Fume-hoods and other open-face containment devices are acceptable when face velocities of at least 1 m/s (200 feet/minute) are achieved.
Partitions, barriers, and other partial containment technologies are required to prevent migration of the material to uncontrolled areas. For non-routine emergencies maximum local and general exhaust are necessary. Air contaminants generated in the workplace possess varying "escape" velocities which, in turn, determine the "capture velocities" of fresh circulating air required to effectively remove the contaminant.

Type of Contaminant:	Air Speed:
solvent, vapors, etc. evaporating from tank (in still air)	0.25-0.5 m/s (50-100 f/min.)
aerosols, fumes from pouring operations, intermittent container filling, low speed conveyer transfers (released at low velocity into zone of active generation)	0.5-1 m/s (100-200 f/min.)
direct spray, drum filling, conveyer loading, crusher dusts, gas discharge (active generation into zone of rapid air motion)	1-2.5 m/s (200-500 f/min.)

Within each range the appropriate value depends on:

Lower end of the range	Upper end of the range
1: Room air currents minimal or favourable to capture	1: Disturbing room air currents
2: Contaminants of low toxicity or of nuisance value only.	2: Contaminants of high toxicity
3: Intermittent, low production.	3: High production, heavy use
4: Large hood or large air mass in motion	4: Small hood-local control only

Simple theory shows that air velocity falls rapidly with distance away from the opening of a simple extraction pipe. Velocity generally decreases with the square of distance from the extraction point (in simple cases). Therefore the air speed at the extraction point should be adjusted, accordingly, after reference to distance from the contaminating source. The air velocity at the extraction fan, for example, should be a minimum of 1-2.5 m/s (200-500 f/min.) for extraction of gases discharged 2 meters distant from the extraction point. Other mechanical considerations, producing performance deficits within the extraction apparatus, make it essential that theoretical air velocities are multiplied by factors of 10 or more when extraction systems are installed or used.

Section 9 - PHYSICAL AND CHEMICAL PROPERTIES

Fluoxetine Hydrochloride

sc-207693

Material Safety Data Sheet

Hazard Alert Code Key:	EXTREME	HIGH	MODERATE	LOW

PHYSICAL PROPERTIES

Solid.
Mixes with water.

State	Divided solid	Molecular Weight	309.36
Melting Range (°F)	Not available	Viscosity	Not Applicable
Boiling Range (°F)	Not available	Solubility in water (g/L)	Miscible
Flash Point (°F)	Not available	pH (1% solution)	Not available
Decomposition Temp (°F)	Not Available	pH (as supplied)	Not applicable
Autoignition Temp (°F)	Not available	Vapour Pressure (mmHG)	Negligible
Upper Explosive Limit (%)	Not available	Specific Gravity (water=1)	Not available
Lower Explosive Limit (%)	Not available	Relative Vapor Density (air=1)	Not Applicable
Volatile Component (%vol)	Negligible	Evaporation Rate	Not Applicable

APPEARANCE

Crystalline powder; mixes with water.

Section 10 - CHEMICAL STABILITY

CONDITIONS CONTRIBUTING TO INSTABILITY

■
- Presence of incompatible materials.
- Product is considered stable.
- Hazardous polymerization will not occur.

STORAGE INCOMPATIBILITY

■ Avoid reaction with oxidizing agents.

For incompatible materials - refer to Section 7 - Handling and Storage.

Section 11 - TOXICOLOGICAL INFORMATION

fluoxetine hydrochloride

TOXICITY AND IRRITATION

■ unless otherwise specified data extracted from RTECS - Register of Toxic Effects of Chemical Substances.

TOXICITY	IRRITATION
Oral (rat) LD50: 452 mg/kg	
Oral (mouse) LD50: 248 mg/kg	
Intraperitoneal (mouse) LD50: 100 mg/kg	
Oral (man) TDLo: 3.73 mg/kg/24h - I *	Nil Reported

* Sleep, euphoria, aggression recorded.

Section 12 - ECOLOGICAL INFORMATION

Refer to data for ingredients, which follows:
FLUOXETINE HYDROCHLORIDE:
■ Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
■ Do NOT allow product to come in contact with surface waters or to intertidal areas below the mean high water mark. Do not contaminate water when cleaning equipment or disposing of equipment wash-waters.
Wastes resulting from use of the product must be disposed of on site or at approved waste sites.
■ For selective serotonin reuptake inhibitors (SSRIs):

Hazard Alert Code Key:	EXTREME	HIGH	MODERATE	LOW

Selective serotonin reuptake inhibitors (SSRIs) are a major class of widely prescribed antidepressants and obsessive-compulsive regulators that includes Prozac, Zoloft, Luvox, and Paxil.
The function of serotonin in a wide array of aquatic creatures could prove highly significant in any discussion of the importance of low levels of pharmaceuticals in the environment. The potential for
dramatic physiologic effects on nontarget species (such as invertebrates) by low (ppb) concentrations of pharmaceuticals is the subject of many studies. Serotonin is a biogenic amine common in both vertebrate and invertebrate nervous systems. SSRIs increase serotonin neurotransmission by inhibiting its reuptake at the synapses by inhibiting the transporter enzymes. In addition to playing a key role in mammalian neurotransmission, serotonin is involved in a wide array of physiologic regulatory roles in molluscs, among most other creatures. For bivalves, reproductive functions including spawning, oocyte maturation, and parturition are regulated by serotonin Serotonin controls a wide spectrum of additional behaviors and reflexes in molluscs, including heartbeat rhythm, feeding/biting, swimming motor patterns, beating of cilia, and induction of larval metamorphosis. It also stimulates release of various neurohormones in crustaceans (hyperglycemic hormone, red pigment-dispersing hormone, neurodepressing hormone, and molt-inhibiting hormone) and ovarian maturation. It has long been known that serotonin at concentrations of 10-4 to 10-3 M (~0.18-1.8 g/L) induces spawning in bivalves. Some commercial farmers make use of this by adding serotonin to induce spawning. Prozac (fluoxetine) and Luvox (fluvoxamine) are the most potent inducers ever found, eliciting spawning behavior in zebra mussels at aqueous concentrations many orders of magnitude lower than serotonin. Fluoxetine elicited significant spawning in male mussels at concentrations of 10-7 M (~150 ug/L); females were an order of magnitude less sensitive at 10-6 M. Fluvoxamine was the most potent of the SSRIs, eliciting significant spawning in male mussels, at 10-9 M (~0.318 ug/L); females were two orders of magnitude less sensitive, at 10-7 M. In males, spawning was complete in the first hour, while females were slower (within 2 hr). Paxil (paroxetine) was the least potent of these three SSRIs, eliciting male spawning, but to a lesser degree, at 10-6 M, and having no inducing effect on females at any concentration. It should be noted that the evidence is not clear whether these compounds are indeed acting as SSRIs, or via some other mechanism. It is also unknown how these compounds are taken up by molluscs. In another study, fluvoxamine induces significant parturition in fingernail clams at 1 nM; 1 nM fluvoxamine also potentiated the effect of 10 uM 5-hydroxytryptophan (5-HT, a precursor of serotonin) by almost 5-fold. Paroxetine was less potent, requiring a concentration of 10 uM to effect significant parturition. In contrast, even at concentrations of 100 uM, fluoxetine displayed no effect, although it was capable at 5 uM of potentiating 5-HT at concentrations that were otherwise subthreshold. It is interesting that the order of potency for inducing parturition in clams differs from the order for induction of spawning in mussels (above). This points to the complexity of considering any approach involving extrapolations from one species to another or from one drug to another within a given class.
In crustaceans, fluoxetine significantly potentiates the effect of 5-HT in crayfish, enhancing the release of ovary-stimulating hormone, which results in larger oocytes with enhanced amounts of vitellin; any ecologic consequences of higher vitellin protein levels are unknown.
Similarly, in fiddler crabs, fluoxetine at a dose of 125 nmol stimulates (through 5-HT) the production of gonad-stimulating hormone, which accelerates testicular maturation . It is clear that aquatic life can be exquisitely sensitive to at least some of this class of compounds.
Although some SSRIs are extremely potent, others have almost no effect, which possibly makes the approach of assessing ecologic risk on a class-by-class basis infeasible.
Concentration of SSRIs plays a complicated role with respect to effects. For example, while injected fluoxetine induced significant metamorphosis in a gastropod, 10-4 M induced less metamorphosis than 10-6 M. Simple extrapolations of effects from higher concentrations do not necessarily have any relevance to effects at lower concentrations.
The potential for SSRIs to elicit subtle effects on aquatic life is further extended by serotonin reuptake mechanisms that also are a factor in snails and squids , particularly in the regulation of aggression . Yet another example of a subtle effect that would go unnoticed is the fighting behavior of lobsters, in which serotonin causes behavior reversal by stimulating subordinates to engage in fighting against dominants by reducing their propensity to retreat .
■ DO NOT discharge into sewer or waterways.

Section 13 - DISPOSAL CONSIDERATIONS

Disposal Instructions

All waste must be handled in accordance with local, state and federal regulations.
¦ Puncture containers to prevent re-use and bury at an authorized landfill.
Legislation addressing waste disposal requirements may differ by country, state and/ or territory. Each user must refer to laws operating in their area. In some areas, certain wastes must be tracked.
A Hierarchy of Controls seems to be common - the user should investigate:

- Reduction
- Reuse
- Recycling
- Disposal (if all else fails)

This material may be recycled if unused, or if it has not been contaminated so as to make it unsuitable for its intended use. Shelf life considerations should also be applied in making decisions of this type. Note that properties of a material may change in use, and recycling or reuse may not always be appropriate.
DO NOT allow wash water from cleaning equipment to enter drains. Collect all wash water for treatment before disposal.

- Recycle wherever possible.
- Consult manufacturer for recycling options or consult Waste Management Authority for disposal if no suitable treatment or disposal facility

can be identified.

- Dispose of by: Burial in a licensed land-fill or Incineration in a licensed apparatus (after admixture with suitable combustible material)
- Decontaminate empty containers. Observe all label safeguards until containers are cleaned and destroyed.

Section 14 - TRANSPORTATION INFORMATION

DOT:

Symbols:	None	Hazard class or Division:	6.1
Identification Numbers:	UN3249	PG:	III
Label Codes:	6.1	Special provisions:	T1, TP33
Packaging: Exceptions:	153	Packaging: Non-bulk:	213
Packaging: Exceptions:	153	Quantity limitations: Passenger aircraft/rail:	5 kg
Quantity Limitations: Cargo aircraft only:	5 kg	Vessel stowage: Location:	C
Vessel stowage: Other:	40		

Hazardous materials descriptions and proper shipping names:
Medicine, solid, toxic, n.o.s.

Air Transport IATA:

ICAO/IATA Class:	6.1	ICAO/IATA Subrisk:	None
UN/ID Number:	3249	Packing Group:	III
Special provisions:	A3		

Shipping Name: MEDICINE, SOLID, TOXIC, N.O.S.(CONTAINS FLUOXETINE HYDROCHLORIDE)

Maritime Transport IMDG:

IMDG Class:	6.1	IMDG Subrisk:	None
UN Number:	3249	Packing Group:	III
EMS Number:	F-A,S-A	Special provisions:	221 223 944
Limited Quantities:	5 kg		

Shipping Name: MEDICINE, SOLID, TOXIC, N.O.S.(contains fluoxetine hydrochloride)

Section 15 - REGULATORY INFORMATION

fluoxetine hydrochloride (CAS: 56296-78-7,59333-67-4) is found on the following regulatory lists;
"OSPAR List of Substances of Possible Concern","US - Maine Chemicals of High Concern List"

Section 16 - OTHER INFORMATION

LIMITED EVIDENCE

■ Inhalation may produce health damage*.
* (limited evidence).

Ingredients with multiple CAS Nos

Ingredient Name	CAS

Fluoxetine Hydrochloride

sc-207693

Material Safety Data Sheet

Hazard Alert Code Key:	EXTREME	HIGH	MODERATE	LOW

fluoxetine hydrochloride 56296-78-7, 59333-67-4

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■ Classification of the mixture and its individual components has drawn on official and authoritative sources as well as independent review by the Chemwatch Classification committee using available literature references.
A list of reference resources used to assist the committee may be found at:
www.chemwatch.net/references.

■ The (M)SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings. Risks may be determined by reference to Exposures Scenarios. Scale of use, frequency of use and current or available engineering controls must be considered.

Issue Date: Oct-28-2009

Print Date:May-22-2010