Escitalopram

sc-357349

Material Safety Data Sheet

Hazard Alert Code Key: EXTREME HIGH MODERATE LOW

Section 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME
Escitalopram

STATEMENT OF HAZARDOUS NATURE

NFPA

SUPPLIER
Santa Cruz Biotechnology, Inc.
2145 Delaware Avenue
Santa Cruz, California 95060
800.457.3801 or 831.457.3800

EMERGENCY:
ChemWatch
Within the US & Canada: 877-715-9305
Outside the US & Canada: +800 2436 2255
(1-800-CHEMCALL) or call +613 9573 3112

SYNONYMS
C20-H21-F-N2-O, "(S)-1-[3-(dimethylamino)propyl]-1-(4-fluorophenyl)-1, 3-", dihydroisobenzofuran-5-carbonitrile, "5-Isobenzofurancarbonitrile, 1-(3-(dimethylamino)propyl)-1-(4-", "fluorophenyl)-1, 3-dihydro-, (1S)-", "citalopram enantiomer", S-(+)-Cctalopram, Cipralex, Gaudium, Recordati, Lexapro, "selective serotonin reuptake inhibitor (SSRI)"

Section 2 - HAZARDS IDENTIFICATION

CHEMWATCH HAZARD RATINGS

<table>
<thead>
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<th></th>
<th>Min</th>
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<tbody>
<tr>
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<tr>
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<tr>
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<tr>
<td>Reactivity:</td>
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<tr>
<td>Chronic:</td>
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CANADIAN WHMIS SYMBOLS
EMERGENCY OVERVIEW

RISK
Possible risk of harm to the unborn child.
Very toxic to aquatic organisms.

POTENTIAL HEALTH EFFECTS

ACUTE HEALTH EFFECTS

SWALLOWED
- Accidental ingestion of the material may be damaging to the health of the individual.
- Aromatic nitriles, unlike aliphatic nitriles, do not appear to liberate cyanide within the body.
- 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. Neonatal 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.[7]

EYE
■ Although the material is not thought to be an irritant, direct contact with the eye may cause transient discomfort characterized by tearing or conjunctival redness (as with windburn). Slight abrasive damage may also result.

SKIN
■ Skin contact with the material may damage the health of the individual; systemic effects may result following absorption.
■ There is some evidence to suggest that this material can cause inflammation of the skin on contact in some persons.
■ This material is a photosensitizer. Certain individuals working with this substance may show allergic reaction of the skin under sunlight.

■ 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 either adverse health effects or irritation of the respiratory tract following inhalation (as classified using animal models). Nevertheless, adverse effects have been produced following exposure of animals by at least one other route and good hygiene practice requires that exposure be kept to a minimum and that suitable control measures be used in an occupational setting.
■ 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
■ 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.

Limited evidence suggests that repeated or long-term occupational exposure may produce cumulative health effects involving organs or biochemical systems.

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.

Section 3 - COMPOSITION / INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>NAME</th>
<th>CAS RN</th>
<th>%</th>
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<tr>
<td>escitalopram</td>
<td>128196-01-0</td>
<td>&gt;98</td>
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</table>

Section 4 - FIRST AID MEASURES

SWALLOWED
· If swallowed do NOT induce vomiting. · If vomiting occurs, lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration.

EYE
· If this product comes in contact with the eyes: · Wash out immediately with fresh 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.
SKIN
- If skin contact occurs: · Immediately remove all contaminated clothing, including footwear · Flush skin and hair with running water (and soap if available).

INHALED
- If dust is inhaled, remove from contaminated area. · Encourage patient to blow nose to ensure clear passage of breathing. · If irritation or discomfort persists seek medical attention.

NOTES TO PHYSICIAN
- 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 serotonin 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 effects following SSRIs overdose 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
  · such 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.

Section 5 - FIRE FIGHTING MEASURES

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<tr>
<td>Specific Gravity (water=1):</td>
<td>Not Available</td>
</tr>
<tr>
<td>Lower Explosive Limit (%):</td>
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EXTINGUISHING MEDIA
- Foam.
- Dry chemical powder.

FIRE FIGHTING
- Alert Emergency Responders and tell them location and nature of hazard.
- Wear breathing apparatus plus protective gloves.
- When any large container (including road and rail large container) is involved in a fire, consider evacuation by 100 metres in all directions.
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.

Combustion products include: carbon monoxide (CO), carbon dioxide (CO2), hydrogen fluoride, nitrogen oxides (NOx), other pyrolysis products typical of burning organic material.

FIRE INCOMPATIBILITY

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

PERSONAL PROTECTION

Glasses:
Chemical goggles.

Gloves:

Respirator:
Particulate

MINOR SPILLS

- Environmental hazard - contain spillage.
- 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.
- 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

- Environmental hazard - contain spillage.
- Moderate hazard.
- CAUTION: Advise personnel in area.
- Alert Emergency Responders and tell them location and nature of hazard.

RECOMMENDED STORAGE METHODS

- Glass container.
- Polyethylene or polypropylene container.
- Check all containers are clearly labelled and free from leaks.

STORAGE REQUIREMENTS

- Observe manufacturer's storing and handling recommendations.

EXPOSURE CONTROLS

The following materials had no OELs on our records
- escitalopram: CAS:128196-01-0

PERSONAL PROTECTION
RESPIRATOR
Particulate
Consult your EHS staff for recommendations

EYE
- When handling very small quantities of the material eye protection may not be required.
- 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 lenses 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.
Experience indicates that the following polymers are suitable as glove materials for protection against undissolved, dry solids, where abrasive particles are not present.
  - polychloroprene
  - nitrile rubber
  - butyl rubber
  - fluorocautchouc
  - polyvinyl chloride
Gloves should be examined for wear and/or degradation constantly.

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.

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.

Section 9 - PHYSICAL AND CHEMICAL PROPERTIES

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<td>Volatile Component (%vol)</td>
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<td>Evaporation Rate</td>
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APPEARANCE
White powder; does not mix well with water.

**Section 10 - CHEMICAL STABILITY**

**CONDITIONS CONTRIBUTING TO INSTABILITY**
- Presence of incompatible materials.
- Product is considered stable.

**STORAGE INCOMPATIBILITY**
- Avoid reaction with oxidizing agents.

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

**Section 11 - TOXICOLOGICAL INFORMATION**

**ESCITALOPRAM**

**TOXICITY AND IRRITATION**

**ESCITALOPRAM:**
- No significant acute toxicological data identified in literature search.

**Section 12 - ECOLOGICAL INFORMATION**

Very toxic to aquatic organisms.
This material and its container must be disposed of as hazardous waste.
Avoid release to the environment.
Refer to special instructions/safety data sheets.

**Section 13 - DISPOSAL CONSIDERATIONS**

**Disposal Instructions**
All waste must be handled in accordance with local, state and federal regulations.
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.

**Section 14 - TRANSPORTATION INFORMATION**

**DOT:**
Symbols: G Hazard class or Division: 9
Identification Numbers: UN3077 PG: III
Label Codes: 9 Special provisions: 8, 146, 335, B54, IB8, IP3, N20, T1, TP33
Packaging: Exceptions: 155 Packaging: Non-bulk: 213
Packaging: Exceptions: 155 Quantity limitations: No limit
Passenger aircraft/rail:
Quantity Limitations: Cargo No limit Vessel stowage: Location: A
aircraft only:
Vessel stowage: Other: None
Hazardous materials descriptions and proper shipping names:
Environmentally hazardous substance, solid, n.o.s

Air Transport IATA:
ICAO/IATA Class: 9 ICAO/IATA Subrisk: None
UN/ID Number: 3077 Packing Group: III
Special provisions: A97
Cargo Only
Packing Instructions: 911 Maximum Qty/Pack: 400 kg
Passenger and Cargo Passenger and Cargo
Packing Instructions: 911 Maximum Qty/Pack: 400 kg
Passenger and Cargo Limited Quantity Passenger and Cargo Limited Quantity
Packing Instructions: Y911 Maximum Qty/Pack: 30 kg G
Shipping Name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. *(CONTAINS ESCITALOPRAM)

Maritime Transport IMDG:
IMDG Class: 9 IMDG Subrisk: None
UN Number: 3077 Packing Group: III
EMS Number: F-A , S-F Special provisions: 179 274 335 909
Limited Quantities: 5 kg Marine Pollutant: Yes
Shipping Name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.

Section 15 - REGULATORY INFORMATION

No data for escitalopram (CAS: , 128196-01-0)

Section 16 - OTHER INFORMATION

LIMITED EVIDENCE

- Skin contact and/or ingestion may produce health damage*.
- Cumulative effects may result following exposure*.
- May produce skin discomfort*.
* (limited evidence).

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- Classification of the preparation 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.

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