SAFETY DATA SHEET

1. Identification

Product identifier
Symbyax®

Other means of identification

Item Code
B02079, B02081, ND1086, ND1087, ND1088, ND1089, PU3230, PU3231, PU3232, PU3233, PU3234, UC9560, UC9561, UC9562, UC9563

Synonyms
10H-Thieno[2,3-b][1,5]benzodiazepine, 2-methyl-4-(4-methyl-1-piperazinyl)- *
Benzenepropanamine, N-methyl-gamma-[4-(trifluoromethyl)phenoxy]-, hydrochloride *
110140/170053 Formulation * LY900000 * OFC Capsules * Olanzapine Fluoxetine Capsule Mix

Recommended use
Pharmaceutical

Recommended restrictions
None known.

Manufacturer/Importer/Supplier/Distributor information

Manufacturer
Eli Lilly and Company

Address
Lilly Corporate Center
Indianapolis, IN 46285

Telephone
Phone: +1-317-276-2000

E-mail
lilly_msds@lilly.com

Emergency phone number
CHEMTREC: +1-800-424-9300

2. Hazard(s) identification

Not classified.

Physical hazards

Health hazards
Acute toxicity, oral Category 4
Acute toxicity, inhalation Category 4
Skin corrosion/irritation Category 2
Serious eye damage/eye irritation Category 1
Sensitization, skin 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

H302
Harmful if swallowed.

H315
Causes skin irritation.

H317
May cause an allergic skin reaction.

H318
Causes serious eye damage.

H332
Harmful if inhaled.

H336
May cause drowsiness or dizziness.

H373
May cause damage to organs (Liver, Blood) through prolonged or repeated exposure.

Precautionary statement

Prevention
P280
Wear protective gloves/protective clothing/eye protection/face protection.

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

IF ON SKIN: Wash with plenty of soap and water.

IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Immediately call a POISON CENTER or doctor/physician.

Storage
Not available.

Disposal
Not available.

Hazard(s) not otherwise classified (HNOC)
None known.

Supplemental information
None.

### 3. Composition/information on ingredients

**Mixtures**

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Common name and synonyms</th>
<th>CAS number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluoxetine Hydrochloride</td>
<td>(3S)-N-methyl-3-phenyl-3-[4-(trifluoromethyl)phenoxy]propan-1-amine hydrochloride</td>
<td>56296-78-7</td>
<td>12 - 19</td>
</tr>
<tr>
<td>Olanzapine</td>
<td>2-methyl-4-(4-methylpiperazin-1-yl)-10H-thieno[2,3-b][1,5]benzodiazepine</td>
<td>132539-06-1</td>
<td>1 - 6</td>
</tr>
<tr>
<td></td>
<td>10H-Thieno[2,3-b][1,5]benzodiazepine, 2-methyl-4-(4-methyl-1-piperazinyl)-</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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
Harmful if swallowed. Harmful if inhaled. Causes eye burns. May cause allergic skin reaction. May cause drowsiness or dizziness. Increased heart rate. Seizures. May cause damage to the liver. Risk of damage to blood system. Symptoms reported in olanzapine overdose include changes in heart rate and rhythm, slurred speech, reduced level of consciousness ranging from sedation to coma, convulsion, and muscle rigidity.

#### Indication of immediate medical attention and special treatment needed
Olanzapine fluoxetine combination - In managing overdose, consider the possibility of multiple drug involvement. Symptomatic treatment and monitoring of vital organ function should be instituted according to clinical presentation, including treatment of hypotension and circulatory collapse and support of respiratory function. Do not use epinephrine, dopamine, or sympathomimetic agents with beta-agonist activity since beta stimulation may worsen hypotension.

- Olanzapine - There is no specific antidote for olanzapine. Induction of emesis is not recommended. Standard procedures for management of overdose may be indicated (i.e. gastric lavage, administration of activated charcoal). The concomitant administration of activated charcoal was shown to reduce the oral bioavailability of olanzapine by 50 to 60%. Symptomatic treatment and monitoring of vital organ function should be instituted according to clinical presentation, including treatment of hypotension and circulatory collapse and support of respiratory function. Do not use epinephrine, dopamine, or other sympathomimetic agents with beta-agonist activity since beta stimulation may worsen hypotension.

- 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.

### 5. Fire-fighting measures

**Suitable extinguishing media**
Water. Carbon dioxide (CO2). Dry chemical.
Unsuitable extinguishing media
None known.

Specific hazards arising from the chemical
Hazardous decomposition products formed under fire conditions.

Special protective equipment and precautions for firefighters
Wear self-contained breathing apparatus and protective clothing.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures
Wear suitable protective clothing, gloves and eye/face protection. Do not breathe dust. See Section 8 of the SDS for Personal Protective Equipment.

Methods and materials for containment and cleaning up
The following are recommended for manufacturing or other situations where exposure to contents may occur. Do not sweep. Vacuum material with appropriate dust collection filter in place. 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. Prevent spilled material from flowing onto adjacent land or into streams, ponds, or lakes.

7. Handling and storage

Precautions for safe handling
Do not get in eyes and avoid contact with skin and clothing. Do not breathe dust. Use only with adequate ventilation. Wear personal protective equipment. Wash hands thoroughly after handling. 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

<table>
<thead>
<tr>
<th>Lilly (LEG) Components</th>
<th>Type</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluoxetine Hydrochloride (CAS 56296-78-7)</td>
<td>TWA (12hrs)</td>
<td>30 ug/m3</td>
</tr>
<tr>
<td></td>
<td>TWA (8hrs)</td>
<td>50 ug/m3</td>
</tr>
<tr>
<td>Olanzapine (CAS 132539-06-1)</td>
<td>STEG (15min)</td>
<td>114 ug/m3</td>
</tr>
<tr>
<td></td>
<td>TWA (12hrs)</td>
<td>38 ug/m3</td>
</tr>
<tr>
<td></td>
<td>TWA (8hrs)</td>
<td>50 ug/m3</td>
</tr>
</tbody>
</table>

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

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

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

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
Capsules containing slightly yellow to yellow powder

Physical state
Solid.

Form
Capsules

Color
Yellow
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: Not 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: No oxidizing properties.

10. Stability and reactivity

Reactivity: Not water reactive.

Chemical stability: Material is stable under normal conditions.

Possibility of hazardous reactions: Hazardous polymerization does not occur.

Conditions to avoid: None known.

Incompatible materials: Strong oxidizing agents.

Hazardous decomposition products: Hazardous decomposition products formed under fire conditions.

11. Toxicological information

Information on toxicological effects

Acute toxicity: Harmful if swallowed. Harmful if inhaled.

<table>
<thead>
<tr>
<th>Components</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluoxetine Hydrochloride</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dermal</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LD50</td>
<td>Rabbit</td>
<td>&gt; 500 mg/kg</td>
</tr>
<tr>
<td>Inhalation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LC50</td>
<td>Rat</td>
<td>898 mg/m3, 1 h</td>
</tr>
<tr>
<td>Components</td>
<td>Species</td>
<td>Test Results</td>
</tr>
<tr>
<td>-------------</td>
<td>-----------</td>
<td>----------------</td>
</tr>
<tr>
<td>Oral</td>
<td>Monkey</td>
<td>&gt; 50 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Mouse</td>
<td>248 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Rat</td>
<td>451 mg/kg</td>
</tr>
</tbody>
</table>

Olanzapine (CAS 132539-06-1)

<table>
<thead>
<tr>
<th>Acute</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Dermal</td>
<td>Rabbit</td>
<td>&gt; 200 mg/kg</td>
</tr>
</tbody>
</table>

| Inhalation  | Rat       | > 880 mg/m³, 4 h |

| Oral        | Monkey    | > 100 mg/kg     |
|             |           | 177 mg/kg       |

**Skin corrosion/irritation**

- Rabbit: No irritation (Olanzapine) (Fluoxetine hydrochloride)
- Skin irritation has been reported with occupational exposure. (Fluoxetine hydrochloride)

**Serious eye damage/eye irritation**

- Rabbit: Corrosive. (Fluoxetine hydrochloride)
- Rabbit: Irritating. (Olanzapine)

**Respiratory or skin sensitization**

**Respiratory sensitization**

- Due to lack of data the classification is not possible.

**Skin sensitization**

- Did not cause sensitization on laboratory animals. Confirmed cases of allergic contact dermatitis have been reported. Symptoms have included rash with redness, swelling, and scaling of the affected skin areas. Positive reactions have been verified by patch testing with olanzapine (0.1%). (Olanzapine)

**Germ cell mutagenicity**

- Result in genetic toxicity assays (in vitro and in vivo): Negative (Fluoxetine hydrochloride and Olanzapine)

**Carcinogenicity**

- Animal testing did not show any carcinogenic effects. (Fluoxetine hydrochloride)
- Olanzapine produced mammary tumors in female rats and female mice. This is consistent with effects of compounds that elevate prolactin levels in rodents. There is no clear understanding of the role of elevated prolactin in human mammary carcinogenesis. (Olanzapine)
- Based on available data, the classification criteria are not met.


- 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)

- Decreased mating activity due to sedation. Decreased fertility, abnormal reproductive cycles, and reproductive tissue changes can be linked to elevations of prolactin levels. The clinical effects of such elevations are unknown for humans. Embryo and fetal toxicity occurred only at maternally toxic doses. (Olanzapine)

- Based on available data, the classification criteria are not met.
Specific target organ toxicity - single exposure
Narcotic effects. May cause drowsiness or dizziness. (Fluoxetine hydrochloride and Olanzapine)

Specific target organ toxicity - repeated exposure
Liver effects (reversible increases in serum enzymes, slight hepatic fat deposition, tissue changes). (Fluoxetine hydrochloride)
Animal studies have reported the following effects: Central nervous system effects. Heart effects. Blood effects. (Olanzapine)

Aspiration hazard
No aspiration toxicity classification

Further information
Olanzapine fluoxetine combination - No new or unexpected toxicity resulting from co-administration of olanzapine and fluoxetine were reported in rats or dogs dosed orally for 3 months. In animals, exposure to olanzapine caused nervous system effects (sedation), increased heart rate, and decreased circulating blood cell counts. Liver effects such as reversible increases in serum enzymes and tissue changes were observed following exposure to fluoxetine.

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.

<table>
<thead>
<tr>
<th>Components</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluoxetine Hydrochloride (CAS 56296-78-7)</td>
<td>Selenastrum capricornutum (new name Pseudokirchnerella subca</td>
<td>1.2 µg/l</td>
</tr>
<tr>
<td>Other</td>
<td>NOEC</td>
<td></td>
</tr>
<tr>
<td>Acute</td>
<td>IC50</td>
<td>1000 mg/l Bacteria (Soil)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>250 mg/l Blue-green algae</td>
</tr>
<tr>
<td></td>
<td></td>
<td>64 mg/l Mold</td>
</tr>
<tr>
<td></td>
<td></td>
<td>64 mg/l Bacteria (n-fixing) (Azotobacter chroococcum)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>64 mg/l Fungus</td>
</tr>
<tr>
<td>Other</td>
<td>EC50</td>
<td>Selenastrum capricornutum (new name Pseudokirchnerella subca</td>
</tr>
<tr>
<td>Aquatic</td>
<td>Acute</td>
<td></td>
</tr>
<tr>
<td>Crustacea</td>
<td>IC50</td>
<td>Daphnia magna</td>
</tr>
<tr>
<td>Fish</td>
<td>LC50</td>
<td>Rainbow Trout</td>
</tr>
<tr>
<td>Olanzapine (CAS 132539-06-1)</td>
<td>NOEC</td>
<td>100 mg/l, 3 h Sewage microorganisms (highest concentration tested)</td>
</tr>
<tr>
<td>Other</td>
<td>NOEC</td>
<td>Pseudokirchnerella subcapitata</td>
</tr>
<tr>
<td></td>
<td></td>
<td>0.9 mg/l, 14 d (based on mean measured concentrations)</td>
</tr>
<tr>
<td>Acute</td>
<td>EC50</td>
<td>&gt; 100 mg/l, 3 h Sewage microorganisms (Respiration inhibition)</td>
</tr>
<tr>
<td></td>
<td>IC50</td>
<td>255 mg/l Isolated growth on agar (Microbial growth inhibition)</td>
</tr>
<tr>
<td>Other</td>
<td>EC50</td>
<td>Pseudokirchnerella subcapitata</td>
</tr>
</tbody>
</table>
Components | Species | Test Results
--- | --- | ---
**Aquatic**
Crustacea | NOEC | Daphnia magna
Fish | NOEC | Fathead minnow (Pimephales promelas)
**Acute**
Crustacea | EC50 | Daphnia magna
Fish | LC50 | Rainbow Trout

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

Olanzapine:
- Hydrolysis half-life at 25 C (days): 65, 76, 78 (pH 5, 7, 9)
- Ready hydrolysis (% hydrolyzed after 28 days at 25 C): 31.15, 24.87, 61.85 (pH 5, 7, 9)
- Biodegradation in sludge (28 days):
  - DT50: 7.4 days
  - 1.45% CO2 evolution
  - 6.5% olanzapine remained
- Degradation in aquatic sediment (100 days):
  - Aerobic systems:
    - DT90 from overlying water: 2.6 days
  - Anaerobic systems:
    - 0.3% CO2 evolution
    - DT90 from overlying water: 14.6 to 17.2 days

**Bioaccumulative potential**
- log Kow: < 4.

**Partition coefficient n-octanol / water (log Kow)**
- Fluoxetine Hydrochloride:
  - 0.93, (pH 5)
  - 1.78, (pH 7)
  - 2.63, (pH 9)
- Olanzapine:
  - 0.3, (pH 5)
  - 1.7, (pH 7)
  - 2.1, (pH 9)

**Mobility in soil**
- No data available.

**Other adverse effects**
- Not available.

**Ecotoxicological Properties**

**Drinking Water**

<table>
<thead>
<tr>
<th>Components</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluoxetine Hydrochloride</td>
<td>2.6 µg/l, (Lilly Aquatic Exposure Guideline)</td>
</tr>
<tr>
<td>Olanzapine</td>
<td>2.5 µg/l, (Lilly Aquatic Exposure Guideline)</td>
</tr>
</tbody>
</table>

**Chronic Exposure of Aquatic Organisms**

<table>
<thead>
<tr>
<th>Components</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluoxetine Hydrochloride</td>
<td>0.33 µg/l, (Lilly Aquatic Exposure Guideline)</td>
</tr>
<tr>
<td>Olanzapine</td>
<td>7.4 µg/l, (Lilly Aquatic Exposure Guideline)</td>
</tr>
</tbody>
</table>

**Acute Exposure of Aquatic Organisms**

<table>
<thead>
<tr>
<th>Components</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluoxetine Hydrochloride</td>
<td>2.1 µg/l, (Lilly Aquatic Exposure Guideline)</td>
</tr>
<tr>
<td>Olanzapine</td>
<td>67 µg/l, (Lilly Aquatic Exposure Guideline)</td>
</tr>
</tbody>
</table>

**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

<table>
<thead>
<tr>
<th>UN number</th>
<th>UN3077</th>
</tr>
</thead>
<tbody>
<tr>
<td>UN proper shipping name</td>
<td>Environmentally hazardous substance, solid, n.o.s. (Fluoxetine Hydrochloride, Olanzapine)</td>
</tr>
</tbody>
</table>

Transport hazard class(es)

- Class: 9
- Subsidiary risk: -
- Packing group: III
- Environmental hazards: Yes
- ERG Code: 9L
- Special precautions for user: Not available.
- Other information:
  - Passenger and cargo aircraft: Allowed.
  - Cargo aircraft only: Allowed.

IMDG

<table>
<thead>
<tr>
<th>UN number</th>
<th>UN3077</th>
</tr>
</thead>
<tbody>
<tr>
<td>UN proper shipping name</td>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Fluoxetine Hydrochloride, Olanzapine)</td>
</tr>
</tbody>
</table>

Transport hazard class(es)

- Class: 9
- Subsidiary risk: -
- Packing group: III
- Environmental hazards: Yes
- Marine pollutant: 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

15. Regulatory information

US federal regulations
This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.
CERCLA/SARA Hazardous Substances - Not applicable.
**Material name:** Symbyax®

**Issue date:** 12-11-2014

**Revision date:** 09-04-2015

**Version #:** 02

**Lilly Lab Code:**
- Health: 3
- Fire: 1
- Reactivity: 0
- Special 1: A

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**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.

- Not listed.

**Superfund Amendments and Reauthorization Act of 1986 (SARA)**
- **Hazard categories**
  - Immediate Hazard - Yes
  - Delayed Hazard - Yes
  - Fire Hazard - No
  - Pressure Hazard - No
  - Reactivity Hazard - No

**SARA 313 (TRI reporting)**
- Not regulated.

**Other federal regulations**
- **Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List**
  - Not regulated.

- **Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)**
  - Not regulated.

- **Safe Drinking Water Act (SDWA)**
  - Not regulated.

**US state regulations**
- **US. California Controlled Substances. CA Department of Justice (California Health and Safety Code Section 11100)**
  - Not listed.

- **US. Massachusetts RTK - Substance List**
  - Not regulated.

- **US. New Jersey Worker and Community Right-to-Know Act**
  - Not listed.

- **US. Pennsylvania Worker and Community Right-to-Know Law**
  - Not listed.

- **US. Rhode Island RTK**
  - Not regulated.

- **US. California Proposition 65**
  - **US - California Proposition 65 - CRT: Listed date/Developmental toxin**
    - Olanzapine (CAS 132539-06-1)
    - Listed: October 1, 1992

**International Inventories**

<table>
<thead>
<tr>
<th>Country(s) or region</th>
<th>Inventory name</th>
<th>On inventory (yes/no)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Canada</td>
<td>Domestic Substances List (DSL)</td>
<td>No</td>
</tr>
<tr>
<td>Canada</td>
<td>Non-Domestic Substances List (NDSL)</td>
<td>No</td>
</tr>
<tr>
<td>United States &amp; Puerto Rico</td>
<td>Toxic Substances Control Act (TSCA) Inventory</td>
<td>No</td>
</tr>
</tbody>
</table>

*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).*

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

- **Issue date:** 12-11-2014
- **Revision date:** 09-04-2015
- **Version #:** 02
- **Lilly Lab Code**
  - Health: 3
  - Fire: 1
  - Reactivity: 0
  - Special 1: A
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Revision Information

Exposure controls/personal protection: General hygiene considerations
Physical & Chemical Properties: Multiple Properties
Ecological Information: Ecotox Property Data
Regulatory Information: Risk Phrases - Class.
GHS: Classification