SAFETY DATA SHEET

1. Identification

Product identifier

Symbayx®

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

LY Number

LY900000

Recommended use

Pharmaceutical

Recommended restrictions

None known.

Manufacturer/Importer/Supplier/Distributor information

Manufacturer

Company name

Eli Lilly and Company

Address

Lilly Corporate Center
Indianapolis, IN 46285
United States

Telephone

Phone: +1-317-276-2000

Emergency phone number

CHEMTREC: +1-800-424-9300

E-mail

United States

lilly_msds@lilly.com

2. Hazard(s) identification

Physical hazards

Not classified.

Health hazards

Acute toxicity, oral 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.
H318 Causes serious eye damage.
H317 May cause an allergic skin reaction.
H336 May cause drowsiness or dizziness.
H373 May cause damage to organs (Liver, Blood) through prolonged or repeated exposure.

Precautionary statement

Prevention

P280

Response

P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
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, 2-R-methyl-4-(4-methyl-1-piperazinyl)</td>
<td>132539-06-1</td>
<td>1-6</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. 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.
Hazardous decomposition products formed under fire conditions.

Special protective equipment and precautions for firefighters

Wear self-contained breathing apparatus and protective clothing.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

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

Methods and materials for containment and cleaning up

Do not sweep. Vacuum material with appropriate dust collection filter in place. 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>

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

Biological limit values

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.

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/face shield.

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. The formulated material is not expected to pose an inhalation hazard.

<table>
<thead>
<tr>
<th>Components</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<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>Oral</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LD50</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>
<tr>
<td>Components</td>
<td>Species</td>
<td>Test Results</td>
</tr>
<tr>
<td>------------</td>
<td>---------</td>
<td>--------------</td>
</tr>
<tr>
<td><strong>Acute</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Dermal</strong></td>
<td>Rabbit</td>
<td>&gt; 200 mg/kg</td>
</tr>
<tr>
<td><strong>Inhalation</strong></td>
<td>Rat</td>
<td>&gt; 880 mg/m³, 4 h</td>
</tr>
<tr>
<td><strong>Oral</strong></td>
<td>Monkey</td>
<td>&gt; 100 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Rat</td>
<td>177 mg/kg</td>
</tr>
<tr>
<td><strong>Skin corrosion/irritation</strong></td>
<td>Rabbit: No irritation. (Olanzapine) (Fluoxetine hydrochloride)</td>
<td>Skin irritation has been reported with occupational exposure. (Fluoxetine hydrochloride)</td>
</tr>
<tr>
<td><strong>Serious eye damage/eye irritation</strong></td>
<td>Rabbit: Corrosive. (Fluoxetine hydrochloride)</td>
<td>Rabbit: Irritating. (Olanzapine)</td>
</tr>
<tr>
<td><strong>Respiratory or skin sensitization</strong></td>
<td>Due to lack of data the classification is not possible.</td>
<td></td>
</tr>
<tr>
<td><strong>Respiratory sensitization</strong></td>
<td>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)</td>
<td></td>
</tr>
<tr>
<td><strong>Skin sensitization</strong></td>
<td>Result in genetic toxicity assays (in vitro and in vivo): Negative (Fluoxetine hydrochloride and Olanzapine)</td>
<td></td>
</tr>
<tr>
<td><strong>Germ cell mutagenicity</strong></td>
<td>Animal testing did not show any carcinogenic effects. (Fluoxetine hydrochloride)</td>
<td>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)</td>
</tr>
<tr>
<td><strong>Carcinogenicity</strong></td>
<td>Based on available data, the classification criteria are not met.</td>
<td></td>
</tr>
<tr>
<td><strong>IARC Monographs. Overall Evaluation of Carcinogenicity</strong></td>
<td>Not listed.</td>
<td></td>
</tr>
<tr>
<td><strong>US. National Toxicology Program (NTP) Report on Carcinogens</strong></td>
<td>Not listed.</td>
<td></td>
</tr>
<tr>
<td><strong>Reproductive toxicity</strong></td>
<td>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.</td>
<td></td>
</tr>
</tbody>
</table>
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>NOEC Selenastrum capricornutum (new name Pseudokirchnerella subca)</td>
<td>1.2 µg/l</td>
</tr>
<tr>
<td></td>
<td>Acute EC50 Selenastrum capricornutum (new name Pseudokirchnerella subca)</td>
<td>30.5 µg/l (average specific growth rate)</td>
</tr>
<tr>
<td></td>
<td>IC50 1000 mg/l Bacteria (Soil)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>250 mg/l Blue-green algae</td>
<td></td>
</tr>
<tr>
<td></td>
<td>64 mg/l Bacteria (n-fixing) (Azotobacter chroococcum)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>64 mg/l Mold</td>
<td></td>
</tr>
<tr>
<td></td>
<td>64 mg/l Fungus</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Acute Aquatic Crustacea IC50 Daphnia magna</td>
<td>0.94 mg/l, 48 h</td>
</tr>
<tr>
<td></td>
<td>Fish LC50 Rainbow Trout</td>
<td>1.57 mg/l, 96 h</td>
</tr>
<tr>
<td>Olanzapine (CAS 132539-06-1)</td>
<td>NOEC 100 mg/l, 3 h Sewage microorganisms (highest concentration tested)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Other NOEC Pseudokirchnerella subcapitata</td>
<td>1.7 mg/l, 14 d (based on initial concentration)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>0.9 mg/l, 14 d (based on mean measured concentrations)</td>
</tr>
<tr>
<td></td>
<td>Acute EC50 Selenastrum capricornutum (new name Pseudokirchnerella subca)</td>
<td>&gt; 100 mg/l, 3 h Sewage microorganisms (Respiration inhibition)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>&gt; 14.1 mg/l (average specific growth rate)</td>
</tr>
<tr>
<td></td>
<td>IC50 255 mg/l Isolated growth on agar (Microbial growth inhibition)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Other EC50 Pseudokirchnerella subcapitata</td>
<td>&gt; 14.1 mg/l, 14 d (average specific growth rate) (biomass)</td>
</tr>
</tbody>
</table>

Material name: Symbyax®
4448 Version #: 05 Revision date: 03-18-2019 Issue date: 12-11-2014
SDS US 6 / 9
<table>
<thead>
<tr>
<th>Components</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aquatic</td>
<td>Crustacea NOEC</td>
<td>Daphnia magna</td>
</tr>
<tr>
<td>Fish</td>
<td>NOEC</td>
<td>Fathead minnow (Pimephales promelas)</td>
</tr>
</tbody>
</table>

**Acute**

| Crustacea | EC50 | Daphnia magna | 8 mg/l, 48 h |
| Fish      | LC50 | Rainbow Trout | 1.74 mg/l, 96 h |

**LILLY AQUATIC EXPOSURE GUIDELINES:**

**Fluoxetine Hydrochloride**

- Drinking water LAEG (at the point where surface water is taken for drinking water): 2.6 µg/l
- Acute LAEG (at the edge of the acute mixing zone): 2.1 µg/l
- Chronic LAEG (at the edge of the chronic mixing zone): 0.33 µg/l

**Olanzapine**

- Acute LAEG (at the edge of the acute mixing zone): 67 µg/l
- Chronic LAEG (at the edge of the chronic mixing zone): 7.4 µg/l
- Drinking water LAEG (at the point where surface water is taken for drinking water): 2.5 µg/l

**Persistence and degradability**

**Fluoxetine Hydrochloride:**

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

**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:
    - 4.3% CO2 evolution
    - 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)**

<table>
<thead>
<tr>
<th>Fluoxetine Hydrochloride</th>
<th>0.93, (pH 5)&lt;br&gt;1.78, (pH 7)&lt;br&gt;2.63, (pH 9)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Olanzapine</td>
<td>0.3, (pH 5)&lt;br&gt;1.7, (pH 7)&lt;br&gt;2.1, (pH 9)</td>
</tr>
</tbody>
</table>

**Mobility in soil**

- No data available.

**Other adverse effects**

- Not available.

**13. Disposal considerations**

**Disposal instructions**

- Dispose of contents/container in accordance with local/regional/national/international regulations.

**14. Transport information**

**DOT**

- Not regulated as dangerous goods.

**IATA**

- **UN number**: UN3077
- **UN proper shipping name**: Environmentally hazardous substance, solid, n.o.s. (Fluoxetine Hydrochloride, Olanzapine)
- **Transport hazard class(es)**: 9
Subsidiary risk: -
Packing group: III
Environmental hazards: Yes
ERG Code: 9L
Special precautions for user: Not available.

Other information:
- Passenger and cargo aircraft: Allowed with restrictions.
- Cargo aircraft only: Allowed with restrictions.

IMDG:
- UN number: UN3077
- UN proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Fluoxetine Hydrochloride, Olanzapine)
- 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.
- Marine pollutant: Not available.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

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.

Toxic Substances Control Act (TSCA)
TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)
Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)
Not listed.

SARA 304 Emergency release notification
Not regulated.
OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)
Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)
Classified hazard categories
Acute toxicity (any route of exposure)
Skin corrosion or irritation
Serious eye damage or eye irritation
Respiratory or skin sensitization
Specific target organ toxicity (single or repeated exposure)

SARA 313 (TRI reporting)
Not regulated.

Other federal regulations
Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List
Not regulated.
Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)
Not regulated.

US state regulations
California Proposition 65
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).

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

Issue date 12-11-2014
Revision date 03-18-2019
Version # 05

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

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