SAFETY DATA SHEET

1. Identification

Product identifier **Zyprexa® Tablets**

Other means of identification

Item Code ND1038, ND1023, ND1034, ND1100, TA4453, TA4420, ND1096, QA480U, ND1097, TA4757, TA4756, ND1098, ND1099, TA4117, TA4758, TA4116, ND0998, ND0997, TA4455, TA4454, TA4112, QA479W, MS8293, TA4415, ND1022, TA4456, ND1011, ND1029, TA4115, ND1009, ND1013, ZD4112, UC7656, UC7657, UC7655, UC7652, UC7654, UC7653

Synonyms 10H-Thieno[2,3-b][1,5]benzodiazepine, 2-methyl-4-(4-methyl-1-piperazinyl)- *
2-Methyl-4-(4-methyl-1-piperazinyl)-10H-thieno[2,3-b]
[1,5]benzodiazepine

Recommended use Pharmaceutical

Recommended restrictions None known.

Manufacturer/Importer/Supplier/Distributor information

Manufacturer

Company name Eli Lilly and Company

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Indianapolis, IN 46285
United States

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2. Hazard(s) identification

Physical hazards Not classified.

Health hazards

Acute toxicity, oral	Category 4
Serious eye damage/eye irritation	Category 2B
Sensitization, skin	Category 1
Specific target organ toxicity, single exposure	Category 3 narcotic effects
Specific target organ toxicity, repeated exposure	Category 2 (Blood)

OSHA defined hazards Not classified.

Label elements

Signal word Warning

Hazard statement

H302 Harmful if swallowed.
H317 May cause an allergic skin reaction.
H320 Causes eye irritation.
H336 May cause drowsiness or dizziness.
H373 May cause damage to organs (Blood) through prolonged or repeated exposure.

Precautionary statement

Prevention

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

Response

P301 + P312 IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.
P333 + P313 If skin irritation or rash occurs: Get medical advice/attention.
P337 + P313 If eye irritation persists: Get medical advice/attention.

P363	Wash contaminated clothing before reuse.
Storage	Not available.
Disposal	Not available.
Hazard(s) not otherwise classified (HNOC)	None known.
Supplemental information	Not applicable.

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
Olanzapine	2-methyl-4-(4-methylpiperazin-1-yl)-10H-thieno[2,3-b][1,5]benzodiazepine 10H-Thieno[2,3-b][1,5]benzodiazepine, 2-methyl-4-(4-methyl-1-piperazinyl)-	132539-06-1	0.3 - 34

Composition comments Remaining components of this product are non-hazardous and/or are present at concentrations below reportable levels.

4. First-aid measures

Inhalation Remove to fresh air. If breathing stops, provide artificial respiration. Get medical attention immediately.

Skin contact Wash off immediately with plenty of water. Continue to rinse for at least 15 minutes. Immediately take off all contaminated clothing. Get medical attention if irritation develops and persists.

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.

Ingestion Immediately give large quantities of water to drink. Never give anything by mouth to a victim who is unconscious or is having convulsions. Call a physician immediately.

Most important symptoms/effects, acute and delayed Capsules or tablets are intended for human consumption under guidance of a physician. Irritating to eyes. May cause allergic skin reaction. May cause blood damage. 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 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.

5. Fire-fighting measures

Suitable extinguishing media Carbon dioxide, dry chemical or water.

Unsuitable extinguishing media None known.

Specific hazards arising from the chemical If small particles are generated during further processing, handling, or by other means, may form combustible dust concentrations in air. Fire or excessive heat may produce hazardous decomposition products.

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. See Section 8 of the SDS for Personal Protective Equipment.

Methods and materials for containment and cleaning up The recommendations in this section are intended for manufacturing or other situations where exposure to contents may occur.

Do not sweep. Collect spill using a vacuum cleaner with a HEPA filter. Be aware of potential for dust explosion when using electrical equipment. If vacuum is not available, lightly mist/wet material and remove by mopping or wet wiping.

Environmental precautions Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling Avoid contact with eyes, skin, and clothing. Wash hands thoroughly after handling. See Section 8 of the SDS for Personal Protective Equipment.

Conditions for safe storage, including any incompatibilities Keep container tightly closed in a dry and well-ventilated place. Store at: 20 - 25 C.

8. Exposure controls/personal protection

Occupational exposure limits

Lilly (LEG)

Components	Type	Value
Olanzapine (CAS 132539-06-1)	STEG (15min)	114 ug/m3
	TWA (12hrs)	38 ug/m3
	TWA (8hrs)	50 ug/m3

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

Appropriate engineering controls The recommendations in this section are intended for manufacturing or other situations where exposure to contents may occur.

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

Individual protection measures, such as personal protective equipment

Eye/face protection Safety glasses with side shields recommended. If splash potential or dusty operations, wear goggles/faceshield.

Skin protection

Hand protection Chemical resistant gloves.

Other Chemical-resistant gloves and impermeable body covering to minimize skin contact.

Respiratory protection If the applicable occupational exposure level (OEL) is anticipated to be exceeded, wear an approved respirator with sufficient protection factor to control exposure below the OEL.

Thermal hazards Not available.

General hygiene considerations Engineering controls should be used as the primary means to control workplace exposures. Follow good workplace hygiene practices such as washing hands after handling this material. In production settings, airline-supplied, hood-type respirators are preferred. Shower and change clothing if skin contact occurs.

9. Physical and chemical properties

Appearance

Physical state Solid.

Form Solid.

Color Off-white

Odor Odorless

Odor threshold No data available.

pH Neutral

Melting point/freezing point No data available.

Initial boiling point and boiling range No data available.

Flash point Not applicable.

Evaporation rate No data available.

Flammability (solid, gas) No test data available.

Upper/lower flammability or explosive limits

Flammability limit - lower (%) No data available.

Flammability limit - upper (%) No data available.

Explosive limit - lower (%) No data available.

Explosive limit - upper (%) No data available.

Vapor pressure	Not applicable.
Vapor density	Not applicable.
Relative density	No data available.
Solubility(ies)	
Solubility (water)	Slightly soluble.
Partition coefficient (n-octanol/water)	No data available.
Auto-ignition temperature	No data available.
Decomposition temperature	No data available.
Viscosity	Not applicable.
Other information	
Density	No data available.
Explosive properties	Not explosive
Oxidizing properties	The substance or mixture is not classified as oxidizing.
Percent volatile	No data available.
VOC (Weight %)	No data available.

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

11. Toxicological information

Information on toxicological effects

Acute toxicity Harmful if swallowed.

Components	Species	Test Results
Olanzapine (CAS 132539-06-1)		
Acute		
Dermal		
LD	Rabbit	> 200 mg/kg
Inhalation		
LC0	Rat	> 880 mg/m3, 4 h
Oral		
LD	Monkey	> 100 mg/kg
LD50	Rat	177 mg/kg

Skin corrosion/irritation	Rabbit: No irritation Based on available data, the classification criteria are not met.
Serious eye damage/eye irritation	Rabbit: Irritating. (Olanzapine)
Respiratory or skin sensitization	
Respiratory sensitization	Due to lack of data the classification is not possible. (Olanzapine)
Skin sensitization	Did not cause sensitization on laboratory animals. (Olanzapine) 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%). 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%).
Germ cell mutagenicity	In vitro and in vivo tests did not show mutagenic effects. (Olanzapine) Based on available data, the classification criteria are not met.

Carcinogenicity

Not listed by ACGIH, IARC, NIOSH, NTP OR OSHA.
Based on results of studies in rats and mice, it was concluded that olanzapine is not carcinogenic. Significant findings in oncogenicity studies were limited to an increased incidence of mammary adenocarcinomas in female rats and mice. This is a common finding in rodents treated with agents that increase prolactin secretion and has no direct significance for humans.
Based on available data, the classification criteria are not met.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Reproductive toxicity

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

May cause drowsiness or dizziness. (Olanzapine)

Specific target organ toxicity - repeated exposure

Animal studies have reported the following effects: Central nervous system effects. Heart effects. Blood effects. (Olanzapine)

Aspiration hazard

Not applicable.

Further information

Adverse effects associated with therapeutic use of olanzapine include sleepiness, weight gain, mild temporary increase in serum prolactin, dizziness, weakness, restlessness, increased appetite, swelling of hands and feet, decreased blood pressure when standing, dry mouth and constipation. Mild temporary increases in glucose and liver enzyme levels and blood effects have been seen occasionally. 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.

12. Ecological information

Ecotoxicity

Very toxic to aquatic life with long lasting effects. (Olanzapine)

Components			Test Results
Olanzapine (CAS 132539-06-1)			
	NOEC		100 mg/l, 3 h Sewage microorganisms (highest concentration tested)
Other	NOEC	Pseudokirchnerella subcapitata	1.7 mg/l, 14 d (based on initial concentration)
			0.9 mg/l, 14 d (based on mean measured concentrations)
Acute			
	EC50		> 100 mg/l, 3 h Sewage microorganisms (Respiration inhibition)
	IC50		255 mg/l Isolated growth on agar (Microbial growth inhibition)
Other	EC50	Pseudokirchnerella subcapitata	> 14.1 mg/l, 14 d (average specific growth rate) (biomass)
		Selenastrum capricornutum (new name Pseudokirchnerella subca	> 14.1 mg/l (average specific growth rate)
Aquatic			
Crustacea	NOEC	Daphnia magna	2.4 mg/l, 48 h
			0.027 mg/l, 21 d (chronic growth) (reproduction) (survival)
Fish	NOEC	Fathead minnow (Pimephales promelas)	0.011 mg/l
		Rainbow Trout	0.43 mg/l, 96 h
Acute			
Crustacea	EC50	Daphnia magna	8 mg/l, 48 h
Fish	LC50	Rainbow Trout	1.74 mg/l, 96 h

Persistence and degradability 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% CO_2 evolution
6.5% olanzapine remained
Degradation in aquatic sediment (100 days):
Aerobic systems:
4.3% CO_2 evolution
DT90 from overlying water: 2.6 days
Anaerobic systems:
0.3% CO_2 evolution
DT90 from overlying water: 14.6 to 17.2 days

Bioaccumulative potential Log Kow: </= 2.1

Partition coefficient n-octanol / water (log Kow)

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

Components	Test Results
Olanzapine	2.5 µg/l, (Lilly Aquatic Exposure Guideline)

Chronic Exposure of Aquatic Organisms

Components	Test Results
Olanzapine	7.4 µg/l, (Lilly Aquatic Exposure Guideline)

Acute Exposure of Aquatic Organisms

Components	Test Results
Olanzapine	67 µg/l, (Lilly Aquatic Exposure Guideline)

13. Disposal considerations

Disposal instructions Dispose in accordance with all applicable 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. (Olanzapine)
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

UN number UN3077
UN proper shipping name Environmentally hazardous substance, solid, n.o.s. (Olanzapine)
Transport hazard class(es)
Class 9
Subsidiary risk -
Packing group III

Environmental hazards

Marine pollutant	Yes
EmS	F-A, S-F
Special precautions for user	Not available.
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not available.

IATA; IMDG

Marine pollutant

15. Regulatory information

US federal regulations

This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.
One or more components are not listed on TSCA.

CERCLA/SARA Hazardous Substances - Not applicable.

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 1910.1001-1050)

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 The California Proposition 65 information reported only applies to the generic class of benzodiazepines. Olanzapine is not listed.

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

Country(s) or region	Inventory name	On inventory (yes/no)*
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)
A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

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

Issue date 03-12-2015

Revision date 09-11-2015

Version # 03

Lilly Lab Code

Health: 2
Fire: 1
Reactivity: 0
Special 1: A

List of abbreviations

LEG: Lilly Exposure Guideline
STEG: Short Term Exposure Guideline
TWA: Time Weighted Average

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Revision Information GHS: Classification