SAFETY DATA SHEET

1. Identification

Product identifier **Zyprexa® Injection**

Other means of identification

Item Code VL7597

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

LY Number LY170053

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

E-mail lilly_sds@lilly.com

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

2. Hazard(s) identification

Physical hazards Not classified.

Health hazards

Acute toxicity, oral	Category 4
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 (Blood)

OSHA defined hazards Not classified.

Label elements

Signal word Danger

Hazard statement

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

Precautionary statement

Prevention

P261 Avoid breathing dust.
P264 Wash thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P272 Contaminated work clothing should not be allowed out of the workplace.
P271 Use only outdoors or in a well-ventilated area.
P280 Wear protective gloves/protective clothing/eye protection/face protection.

Response

P301 + P310 IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician.

P330	Rinse mouth.
P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337 + P313	If eye irritation persists: Get medical advice/attention.
P302 + P352	IF ON SKIN: Wash with plenty of soap and water.
P333 + P313	If skin irritation or rash occurs: Get medical advice/attention.
P362 + P364	Take off contaminated clothing and wash it before reuse.
P312	Call a POISON CENTER or doctor/physician if you feel unwell.

Storage

P405	Store locked up.
P403 + P233	Store in a well-ventilated place. Keep container tightly closed.

Disposal

P501	Dispose of contents/container in accordance with local/regional/national/international regulations.

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

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
Olanzapine	2-methyl-4-(4-methylpiperazine-1-yl)-10H -thieno[2,3-b][1,5]benzodiazepine	132539-06-1	16
Tartaric Acid		87-69-4	5

Remaining components are non-hazardous and/or below required disclosure limits.

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 Causes serious eye damage. May cause allergic skin reaction. May cause blood damage. May cause drowsiness or dizziness.

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.

General information In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

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 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. Do not allow material to freeze.

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 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 Wear goggles/face shield.

Skin protection

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

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.

General hygiene considerations 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. (Lyophilized).

Color Off-white

Odor Odorless

Odor threshold No data available.

pH No data available.

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

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)	No data available.
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	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		
LD50	Rabbit	> 200 mg/kg
Inhalation		
LC0	Rat	> 880 mg/m3, 4 h
Oral		
LD50	Monkey	> 100 mg/kg
	Rat	177 mg/kg
Tartaric Acid (CAS 87-69-4)		
Acute		
Dermal		
LD50	Rat	> 2000 mg/kg
Oral		
LD50	Rat	> 2000 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.

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. (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%).
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.

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

US. National Toxicology Program (NTP) Report on Carcinogens

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.

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

Components		Species	Test Results
Tartaric Acid (CAS 87-69-4)			
Aquatic			
Acute			
Crustacea	EC50	Daphnia magna	93.313 mg/l, 48 hours
Fish	LC50	Danio rerio	> 100 mg/l, 96 hours

LILLY AQUATIC EXPOSURE GUIDELINES:

Olanzapine

Acute LAEG (at the edge of the acute mixing zone):	67 µg/l
Chronic LAEG (at the edge of the chronic mixing zone):	3.4 µg/l
Drinking water LAEG (at the point where surface water is taken for drinking water):	1.1 µg/l

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)
Tartaric Acid	-1.91

Mobility in soil No data available.

Other adverse effects Not available.

13. Disposal considerations

Disposal instructions Dispose in accordance with all applicable regulations.

14. Transport information

DOT

Not regulated as dangerous goods.

IATA

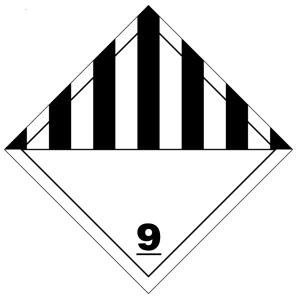
UN number UN3077
UN proper shipping name Environmentally hazardous substance, solid, n.o.s. (Olanzapine)
Transport hazard class(es)
Class 9
Subsidiary risk -
Packing group III
Environmental hazards Yes
ERG Code 9L
Special precautions for user Not available.
Other information
Passenger and cargo aircraft Allowed with restrictions.
Cargo aircraft only Allowed with restrictions.

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.

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 1910.1001-1053)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Classified hazard categories	Acute toxicity (any route of exposure) 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.

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.

California Proposition 65

California Proposition 65 - CRT: Listed date/Developmental toxin

Benzodiazepines (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 02-17-2015

Revision date 02-20-2023

Version # 05

List of abbreviations

ACGIH: American Conference of Governmental Industrial Hygienists.
DOT: Department of Transportation (49 CFR 172.101)
GHS: Globally Harmonized System of Classification and Labeling of Chemicals.
IARC: International Agency for Research on Cancer.
IATA: International Air Transport Association.
IMDG Code: International Maritime Dangerous Goods Code.
LC50: Lethal Concentration 50%.
LD50: Lethal Dose 50%.
LEG: Lilly Exposure Guideline.
LOEC: Lowest observable effect concentration.
NIOSH: National Institute for Occupational Safety & Health.
NOEC: No observed effect concentration.
NTP: National Toxicology Program.
OSHA: Occupational Safety & Health Administration.
STEG: Short Term Exposure Guideline.
TWA: Time Weighted Average

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.

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Revision information Physical & Chemical Properties: Multiple Properties