



SAFETY DATA SHEET

1. Identification

Product identifier	Relprevv™
Other means of identification	
Item Code	VL7635, VL7636, QA509E, QA449S, VL7637, DT7635
CAS number	221373-18-8
Synonyms	Depot-OPM
LY Number	LY170053
LSN Number	426906
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 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	Combustible dust	

Label elements



Signal word Warning

Hazard statement

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

Precautionary statement

Prevention

P261	Avoid breathing dust.
P264	Wash thoroughly after handling.
P270	Do not eat, drink or smoke when using this product.
P271	Use only outdoors or in a well-ventilated area.
P272	Contaminated work clothing should not be allowed out of the workplace.
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 water.
P333 + P313 If skin irritation or rash occurs: Get medical advice/attention.
P304 + P340 + P312 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Get medical assistance if you feel unwell.
P362 + P364 Take off contaminated clothing and wash it before reuse.

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

Substances

Chemical name	Common name and synonyms	CAS number	%
Olanzapine Pamoate Monohydrate	Depot-OPM	221373-18-8	100

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. Wash contaminated clothing before reuse. 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 if irritation develops and persists.

Ingestion Give several glasses of water. Never give anything by mouth to a victim who is unconscious or is having convulsions. Get medical attention if symptoms occur.

Most important symptoms/effects, acute and delayed Irritating to eyes. May cause allergic skin reaction. Harmful if swallowed. 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 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.

General fire hazards Dust may form explosive mixture with air.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures Do not breathe dust. See Section 8 of the SDS for Personal Protective Equipment.

Methods and materials for containment and cleaning up

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

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**

Keep formation of airborne dusts to a minimum. Avoid contact with eyes, 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

Keep container tightly closed in a dry and well-ventilated place.

8. Exposure controls/personal protection**Occupational exposure limits****Lilly (LEG)
Material**

Olanzapine Pamoate
Monohydrate (CAS
221373-18-8)

Type**Value****Form**

STEG (15min)

114 ug/m3

(Olanzapine)

TWA (12hrs)

38 ug/m3

(Olanzapine)

TWA (8hrs)

50 ug/m3

(Olanzapine)

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

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****Physical state**

Solid.

Form

Powder

Color

Yellow

Odor

Odorless

Odor threshold

Not available.

pH

Not available.

Melting point/freezing point

437 - 473 °F (225 - 245 °C) Decomposes

Initial boiling point and boiling range

Not available.

Flash point

Not applicable.

Evaporation rate

Not available.

Flammability (solid, gas)

Not a flammable solid. (OJEC guideline, Test A.10)

Upper/lower flammability or explosive limits**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)**

Insoluble.

Solubility (other)	Dimethyl Sulfoxide (DMSO): Soluble Acetonitrile: Slightly soluble Ethanol: Practically insoluble Methanol: Practically insoluble
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Explosive properties	Not explosive.
Molecular formula	C23 H16 O6 . C17 H20 N4 S . H2 O
Molecular weight	718.83 g/mol
Oxidizing properties	Not oxidizing.

10. Stability and reactivity

Reactivity	Not water reactive.
Chemical stability	This material should not be exposed to temperatures above 135°C (275°F). This temperature is based on a laboratory test (ARC) and assumes near atmospheric pressures and quantities of less than 500 kg (1100 lb) or 208 L (55 gal).
Possibility of hazardous reactions	Hazardous polymerization does not occur.
Conditions to avoid	Excessive heat. Contact with incompatible materials.
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.

Product	Species	Test Results
Relprevv™ (CAS 221373-18-8)		
Acute		
Dermal		
LD50	Rabbit	> 200 mg/kg (Olanzapine)
Inhalation		
LC0	Rat	> 880 mg/m ³ , 4 h (Olanzapine)
Oral		
LD50	Monkey	> 100 mg/kg (Olanzapine)
	Rat	407 mg/kg (calculated) 177 mg/kg (Olanzapine)

Skin corrosion/irritation Rabbit: No irritation. (Olanzapine)
Based on available data, the classification criteria are not met.

Serious eye damage/eye irritation Rabbit: Irritating. (Olanzapine)

Respiratory or skin sensitization

Respiratory sensitization Did not cause sensitization on laboratory animals. (Olanzapine)
Based on available data, the classification criteria are not met.

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 (Olanzapine)
Based on available data, the classification criteria are not met.

Carcinogenicity

Not listed by IARC, NTP, ACGIH 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.

Specific target organ toxicity - repeated exposure

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

Aspiration hazard

No aspiration toxicity classification

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. All data is for Olanzapine.

Product		Species	Test Results
Olanzapine Pamoate Monohydrate (CAS 221373-18-8)	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
	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
	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

A LAEG is the maximum allowable concentration at the point of application that is expected to result in no appreciable risk to populations of aquatic and terrestrial organisms, or to human health.

LILLY AQUATIC EXPOSURE GUIDELINES:

Olanzapine Pamoate Monohydrate

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
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Partition coefficient n-octanol / water (log Kow)

0.3, (pH 5)
1.7, (pH 7)
2.1, (pH 9)

Mobility in soil	No data available.
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Other adverse effects	Not available.
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13. Disposal considerations

Disposal instructions	Dispose of contents/container in accordance with local/regional/national/international regulations.
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14. Transport information

DOT

Not regulated as dangerous goods.

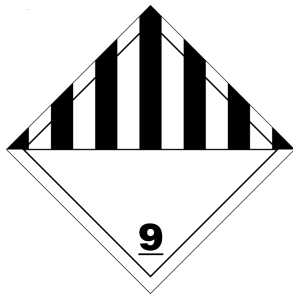
IATA

UN number	UN3077
UN proper shipping name	Environmentally hazardous substance, solid, n.o.s. (Olanzapine Pamoate Monohydrate)
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.

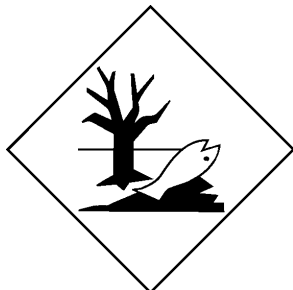
IMDG

UN number	UN3077
UN proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Olanzapine Pamoate Monohydrate)
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.
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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.

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

Combustible dust
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.

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 02-04-2022

Revision date 02-10-2023

Version # 02

List of abbreviations

ACGIH: American Conference of Governmental Industrial Hygienists.
ARC: Accelerating Rate Calorimetry.
DOT: Department of Transportation (49 CFR 172.101)
EC50: Effective Concentration 50%.
GHS: Globally Harmonized System of Classification and Labeling of Chemicals.
HEPA: High Efficiency Particulate Air.
IARC: International Agency for Research on Cancer.
IATA: International Air Transport Association.
IMDG Code: International Maritime Dangerous Goods Code.
LAEG: Lilly Aquatic Exposure Guideline.
LC50: Lethal Concentration 50%.
LD50: Lethal Dose 50%.
LEG: Lilly Exposure Guideline.
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 MERCHANTABILITY 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

This document has undergone significant changes and should be reviewed in its entirety.