



# SAFETY DATA SHEET

## 1. Identification

<b>Product identifier</b>	<b>Cialis®</b>		
<b>Other means of identification</b>			
<b>Item Code</b>	ZD4467, TA4469, TA4468, ND1053, ND1054, ND1105, ND1106, TA4462, TA4463, TA4464, TA4465, VF0371, VF0372, VF0373, VF0378, ZD4125, TA4467, CT4465		
<b>Recommended use</b>	Pharmaceutical		
<b>Recommended restrictions</b>	None known.		
<b>Manufacturer/Importer/Supplier/Distributor information</b>			
<b>Manufacturer</b>			
<b>Company name</b>	Eli Lilly and Company		
<b>Address</b>	Lilly Corporate Center Indianapolis, IN 46285 United States		
<b>Telephone</b>	Phone:	+1-317-276-2000	
<b>E-mail</b>	lilly_msds@lilly.com		
<b>Emergency phone number</b>	CHEMTREC:	+1-800-424-9300	

## 2. Hazard(s) identification

<b>Physical hazards</b>	Not classified.
<b>Health hazards</b>	Not classified.
<b>OSHA defined hazards</b>	Not classified.
<b>Label elements</b>	
<b>Hazard symbol</b>	None.
<b>Signal word</b>	None.
<b>Hazard statement</b>	The mixture does not meet the criteria for classification.
<b>Precautionary statement</b>	
<b>Prevention</b>	Not available.
<b>Response</b>	Not available.
<b>Storage</b>	Not available.
<b>Disposal</b>	Not available.
<b>Hazard(s) not otherwise classified (HNOC)</b>	None known.
<b>Supplemental information</b>	None.

## 3. Composition/information on ingredients

### Mixtures

<b>Chemical name</b>	<b>Common name and synonyms</b>	<b>CAS number</b>	<b>%</b>
Tadalafil	Pyrazinopyridoindoleione (6R,12aR)-6-(1,3-benzodioxol-5-yl)-2-methyl-2,3,6,7,12,12a hexahydropyrazino[1',2':1,6] pyrido[3,4-b]indole-1,4-dione Pyrazino[1',2':1,6]pyrido[3,4-b]indole-1,4-dione, 6-(1,3-benzodioxol-5-yl)- 2,3,6,7,12, 12a-hexahydro-2-methyl-, (6R,12aR)-	171596-29-5	1 - 7

**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.

<b>Skin contact</b>	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.
<b>Eye contact</b>	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.
<b>Ingestion</b>	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.
<b>Most important symptoms/effects, acute and delayed</b>	Headache. Flushing.
<b>Indication of immediate medical attention and special treatment needed</b>	PRE-EXISTING MEDICAL CONDITIONS WHICH MAY BE AGGRAVATED BY EXPOSURE: Individuals on nitrate or alpha blocker therapy.
<b>General information</b>	Intact capsules or tablets are not considered hazardous under normal handling procedures. The recommendations in this section are intended for manufacturing or other situations where exposure to contents may occur.

## 5. Fire-fighting measures

<b>Suitable extinguishing media</b>	Carbon dioxide, dry chemical or water.
<b>Unsuitable extinguishing media</b>	None known.
<b>Specific hazards arising from the chemical</b>	The recommendations in this section are intended for manufacturing or other situations where exposure to contents may occur.  Hazardous decomposition products formed under fire conditions. If small particles are generated during further processing, handling, or by other means, may form combustible dust concentrations in air.
<b>Special protective equipment and precautions for firefighters</b>	Wear self-contained breathing apparatus and protective clothing.

## 6. Accidental release measures

<b>Personal precautions, protective equipment and emergency procedures</b>	Wear suitable protective clothing, gloves and eye/face protection. See Section 8 of the SDS for Personal Protective Equipment.
<b>Methods and materials for containment and cleaning up</b>	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.
<b>Environmental precautions</b>	Avoid discharge into drains, water courses or onto the ground.

## 7. Handling and storage

<b>Precautions for safe handling</b>	Avoid contact with eyes, skin, and clothing. Wash hands thoroughly after handling. See Section 8 of the SDS for Personal Protective Equipment.
<b>Conditions for safe storage, including any incompatibilities</b>	Storage temperature: between 15 C and 30 C.

## 8. Exposure controls/personal protection

### Occupational exposure limits

Lilly (LEG)

Components

	Type	Value
Tadalafil (CAS 171596-29-5)	TWA (12hrs)	13 ug/m3
	TWA (8hrs)	20 ug/m3

### Biological limit values

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

### Appropriate engineering controls

Intact capsules or tablets are not considered hazardous under normal handling procedures and protective equipment is not required. 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, isolator (i.e. glove bag/glove box) and/or closed transfers to maintain airborne levels below occupational exposure level (OEL).

## Individual protection measures, such as personal protective equipment

<b>Eye/face protection</b>	Safety glasses with side shields recommended. If splash potential or dusty operations, wear goggles/faceshield.
<b>Skin protection</b>	
<b>Hand protection</b>	Chemical resistant gloves.
<b>Other</b>	Chemical-resistant gloves and impermeable body covering to minimize skin contact.
<b>Respiratory protection</b>	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.
<b>Thermal hazards</b>	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

<b>Physical state</b>	Solid.
<b>Form</b>	Tablet.
<b>Color</b>	Yellow, Orange or White.

**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 applicable.

**Vapor density** Not applicable.

**Relative density** Not available.

### Solubility(ies)

**Solubility (water)** Not available.

**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

**Oxidizing properties** The substance or mixture is not classified as oxidizing.

## 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

Components	Species	Test Results
Tadalafil (CAS 171596-29-5)		
<b>Acute</b>		
<b>Dermal</b>		
LD	Rabbit	> 1000 mg/kg No mortality. No toxicity.
<b>Oral</b>		
LD	Rat	> 2000 mg/kg No mortality. No toxicity.
<b>Other</b>		
LD	Rat	> 62.5 mg/kg (Intravenous) No mortality. Convulsions.

**Skin corrosion/irritation** Rabbit: Slight irritation.  
Based on available data, the classification criteria are not met.

**Serious eye damage/eye irritation** Rabbit: Slightly irritating.  
Based on available data, the classification criteria are not met.

#### Respiratory or skin sensitization

**Respiratory sensitization** Due to lack of data the classification is not possible.

**Skin sensitization** Due to lack of data the classification is not possible.

**Germ cell mutagenicity** Result in genetic toxicity assays (in vitro and in vivo): Negative  
Based on available data, the classification criteria are not met.

**Carcinogenicity** Not listed by ACGIH, IARC, NIOSH, NTP OR OSHA.  
Based on available data, the classification criteria are not met.

#### IARC Monographs. Overall Evaluation of Carcinogenicity

Not available.

#### OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

#### US. National Toxicology Program (NTP) Report on Carcinogens

Not available.

**Reproductive toxicity** There was no impairment of fertility in male and female rats. In beagle dogs given tadalafil daily for 6 to 12 months at doses of 25 mg/kg/day and above, there were alterations to the seminiferous tubular epithelium that resulted in a decrease in spermatogenesis in some dogs. These findings were not observed in rats or mice. Furthermore, in men taking tadalafil 10 or 20 mg/daily for 6 months, there were no clinically relevant effects on sperm concentration, count, motility, or morphology. Additionally, there were no significant effects of serum levels of testosterone, luteinizing hormone, or follicle stimulating hormone. There was no evidence of teratogenicity, embryotoxicity or fetotoxicity in rats or mice that received up to 1000 mg/kg/day. In a rat pre- and postnatal development study, the observed no effect dose was 30 mg/kg/day.  
Based on available data, the classification criteria are not met.

**Specific target organ toxicity - single exposure** Due to lack of data the classification is not possible.

**Specific target organ toxicity - repeated exposure** Repeated oral doses of tadalafil for more than six months resulted in decreased testicular weight in dogs. The decreased testes weights (reported at doses of 25 mg/kg/day and above in the 12-month study) correlated with degeneration and atrophy of the seminiferous epithelium. Decreased sperm in the epididymes was also reported with aspermia in the most severely affected dogs. No effects on semen parameters reported in humans after six-months of daily dosing (10 or 20 mg/day). When administered orally for 5 or 28 days at 5 mg/kg/day, blood pressure was reduced in rats. No significant findings were reported in rats or mice administered up to 800 mg/kg by oral gavage for up to 3 months. Based on available data, the classification criteria are not met.

**Aspiration hazard** Not applicable.

**Further information**

Based on animal studies with Tadalafil, chronic overexposure by ingestion may cause testicular tissue changes and decreased sperm production. However, two six-month human clinical studies reported no changes in sperm parameters. The most common adverse effects related to drug treatment were headache, lower back pain, and vasodilation (flushing), which can result in transient decreases in blood pressure.

**12. Ecological information****Ecotoxicity**

Harmful to aquatic life with long lasting effects.

Components	Species	Test Results
Tadalafil (CAS 171596-29-5)		
<i>Acute</i>		
	EC50	> 1000 mg/l, 3 hr (Respiration inhibition of activated sludge)
Other	EC50	Pseudokirchnerella subcapitata > 1200 µg/l, 72 hr (yield)
<i>Chronic</i>		
	NOEC	1000 mg/l, 3 hr (Respiration inhibition of activated sludge) (highest concentration tested)
		Chironomus riparius (sediment dwelling midge) 250 mg/kg, 28 d (sediment exposure)
Other	NOEC	Pseudokirchnerella subcapitata > 1200 µg/l, 72 hr (average specific growth rate) (highest concentration tested) 300 µg/l, 72 hr (yield)
<b>Aquatic</b>		
<i>Acute</i>		
Crustacea	EC50	Daphnia magna > 2000 mg/l, 48 hr
	NOEC	Daphnia magna 1200 µg/l, 21 d (Full Life-Cycle Toxicity)
Fish	LC50	Rainbow trout,donaldson trout (Oncorhynchus mykiss) > 2100 µg/l, 96 hr
<i>Chronic</i>		
Crustacea	LOEC	Daphnia magna 1200 µg/l, 21 d (Full Life-Cycle Toxicity)
	NOEC	Daphnia magna 2000 µg/l, 48 hr (highest concentration tested) 480 µg/l, 21 d (Full Life-Cycle Toxicity)
Fish	NOEC	Fathead minnow (Pimephales promelas) 1200 µg/l (embryo and 28 days post hatch) (highest concentration tested) Rainbow trout,donaldson trout (Oncorhynchus mykiss) 2100 µg/l, 96 hr (highest concentration tested)

**Persistence and degradability**

Additional ecological information  
Tadalafil  
24-Hour municipal sewage sludge Kd (g total suspended solids/L): 180  
24-Hour biodegradation in municipal sewage sludge (g total suspended solids/L): none  
Log Koc: 1.95  
Adsorption to sewage sludge after 4 hours, Kd: 183 to 644 (determined at a range of sludge concentrations from 313 to 2500 mg/L)  
Biodegradation in Sludge:  
DT50: 9 days  
Degradation in Aquatic Sediments (108 day aerobic incubation):  
DT50 from overlying water: 3.8 to 4.6 days  
DT50 from water/sediment systems: 70 to 117 days  
24-Hour municipal sewage sludge Kd (g total suspended solids/L): 180  
24-Hour biodegradation in municipal sewage sludge (g total suspended solids/L): none

**Bioaccumulative potential**

No data available on bioaccumulation.

**Partition coefficient n-octanol / water (log Kow)**

Tadalafil 2.32

**Mobility in soil**

No data available.

## Adsorption

### Soil/sediment sorption - log Koc

Tadalafil 1.95

**Other adverse effects** Not available.

## Ecotoxicological Properties

### Drinking Water

#### Components

#### Test Results

Tadalafil 2.5 µg/l, (Lilly Aquatic Exposure Guideline)

### Chronic Exposure of Aquatic Organisms

#### Components

#### Test Results

Tadalafil 200 µg/l, (Lilly Aquatic Exposure Guideline)

### Acute Exposure of Aquatic Organisms

#### Components

#### Test Results

Tadalafil 1000 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

Not regulated as dangerous goods.

### IMDG

Not regulated as dangerous goods.

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code** Not available.

## 15. Regulatory information

**US federal regulations** This product is not known to be a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200. One or more components are not listed on 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 1910.1001-1050)

Not listed.

### Superfund Amendments and Reauthorization Act of 1986 (SARA)

#### Hazard categories

Immediate Hazard - No  
Delayed Hazard - No  
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** California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

**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**

Not Listed.

**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** 11-17-2014

**Revision date** 11-04-2015

**Version #** 06

**Lilly Lab Code** Health: 0  
Fire: 1  
Reactivity: 0

**List of abbreviations**

LEG: Lilly 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 MATERIAL 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** Product and Company Identification: Synonyms