


Section 1: Identification

Common Name/Trade Name	Tadalafil	
Supplier Information	Letco Medical, LLC 1316 Commerce Drive NW Decatur, AL 35601 1 (800) 239-5288 +1 (734) 843-4693	IN CASE OF EMERGENCY: Chemtrec 1 (800) 424- 9300 (24 hours) NSW Poisons Information Centre: 131 126 (24 hours)
Distributor Name	Bella Corp Trading Pty Ltd 6/34 Dominions Road, Ashmore QLD 4214, Australia Telephone: 07 5597 4169 Email: bellacorp@bellacorp.com.au	
Product Synonym(s)	IUPAC Name: (6R,12aR)-6-(1,3-benzodioxol-5-yl)-2-methyl-2,3,6,7,12,12a-hexahydro-1H-pyrazino[1',2':1,6]pyrido[3,4-b]indole-1,4-dione Chemical Name: 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)-	
Relevant Use(s) of Product	Manufacture or Compounding of Substances	

Section 2: Hazards Identification

Classification of Substance or Mixture	Acute toxicity, Oral (Category 4)	
Signal Word	Warning	
Hazard Statement(s)	H302	Harmful if swallowed
Pictogram(s)		
Precautionary Statement(s)	P260 Do not breathe dust/fume/gas/mist/vapours/spray. P264 Wash hands thoroughly after handling. P270 Do not eat, drink or smoke when using this product. P280 Wear protective gloves/protective clothing/eye protection/face protection. P301+P312 IF SWALLOWED Call a POISON CENTER or doctor/physician if you feel unwell. P330 Rinse mouth. P501 Dispose of contents/container to an approved waste disposal plant.	
Hazards Not Otherwise Classified	No data available	
Ingredient(s) with Unknown Toxicity	No data available	

Section 3: Composition/Information on Ingredients

Chemical Name	Tadalafil
Common Name	Tadalafil
CAS Number	171596-29-5
Impurities and/or Stabilizing Additives	N/A

Section 4: First Aid Measures

General Advice	Consult a physician. Show this safety data sheet to the doctor in attendance.
If Inhaled	Remove to fresh air. If breathing is irregular or stopped, administer artificial respiration. Call a physician immediately.
In Case of Skin Contact	Wash off immediately with plenty of water for at least 15 minutes. Take off all contaminated clothing immediately. Get medical attention if irritation develops and persists.
In Case of 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. Obtain medical attention.
If Swallowed	If conscious, give the victim plenty of water to drink. Never give anything by mouth to an unconscious person. Call a physician immediately.
Most Important Symptoms and Effects	Symptoms: None known. Hazards: May cause mild eye/skin irritation.

Section 5: Fire Fighting Measures

Suitable Extinguishing Media	Suitable extinguishing media: Water Carbon dioxide (CO ₂) Dry chemical
Special Hazards Arising From the Substance/Mixture	Dust may form explosive mixture in air. Hazardous decomposition products formed under fire conditions.
Special PPE and/or Precautions for Firefighters	Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

Section 6: Accidental Release Measures

Personal Precautions, Protective Equipment and Emergency Procedures	Wear protective equipment, including eye protection, to avoid exposure (see Section 8 for specific handling precautions).
Methods and Materials Used for Containment	Try to prevent the material from entering drains or water courses. Refer to Sections 11 and 12 for health and environmental hazard information.
Cleanup Procedures	Do not sweep. Preferred method for spill cleanup is by using a HEPA equipped vacuum. 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.

Section 7: Handling and Storage

Precautions for Safe Handling	Avoid contact with skin, eyes and clothing. Wash hands thoroughly after handling. For personal protection see section 8.
Conditions for Safe Storage	Requirements for storage areas and containers: Keep container tightly closed in a dry and well-ventilated place.

Section 8: Exposure Controls/Personal Protection

Components with Workplace Control Parameters	Exposure Limit Values: TWA 0.02 mg/m ³
Appropriate Engineering Controls	Open handling is not recommended. Use appropriate control measures such as fume hood, ventilated enclosure, isolator (eg. glovebag, glovebox), or closed material transfer systems.
PPE - Eye/Face Protection	Safety glasses with side-shields conforming to EN166
PPE - Skin Protection	Chemical-resistant gloves and impermeable body covering to minimize skin contact. Protective gloves complying with EN 374.
PPE - Body Protection	Chemical-resistant gloves and impermeable body covering to minimize skin contact. Protective gloves complying with EN 374.
PPE - Respiratory Protection	Respirator selection must be based on known or anticipated exposure levels, the hazards of the product and the safe working limits of the respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Section 9: Physical and Chemical Properties

Appearance	Practically white solid.
Upper/Lower Flammability or Explosive Limits	No data available
Odor	Odorless
Vapor Pressure	No data available
Odor Threshold	No data available
Vapor Density	No data available
pH	No data available
Relative Density	No data available
Melting Point/Freezing Point	Approximate 300°C
Solubility	1,63 mg/l(pH 4), 1,29 mg/l(pH 7), 1,47 mg/l(pH 9)
Initial Boiling Point and Boiling Range	No data available
Flash Point	No data available
Evaporation Rate	No data available
Flammability (Solid, Gas)	No data available
Partition Coefficient	log Pow: 2,32
Auto-Ignition Temperature	No data available
Decomposition Temperature	No data available
Viscosity	No data available

Section 10: Stability and Reactivity

Reactivity	Reaction with water: Not water reactive.
Chemical Stability	This material should not be packaged or stored above the following temperature: 180°C. This temperature is based on a laboratory test (DSC) and assumes near atmospheric pressures and quantities of less than 500kg (1100 lb) or 208 L (55 gal). For additional information refer to the CHL database on LillyNet or contact the Lilly Chemical Hazards Laboratory.
Possibility of Hazardous Reactions	Hazardous polymerisation does not occur.
Conditions to Avoid	No data available
Incompatible Materials	Strong oxidizing agents
Hazardous Decomposition Products	Hazardous decomposition products formed under fire conditions.

Section 11: Toxicological Information

Acute Toxicity - LD50 Oral	LD (rat) > 2 000 mg/kg
Acute Toxicity - Inhalation	No data available.
Acute Toxicity - Dermal	LD (rabbit) > 1 000 mg/kg. Intravenous - LD (rat) > 62,5 mg/kg
Acute Toxicity - Eye	No data available.
Skin Corrosion/Irritation	rabbit, slight irritation
Serious Eye Damage/Irritation	rabbit, slight irritation
Respiratory or Skin Sensitization	No data available.
Germ Cell Mutagenicity	Result in genetic toxicity assays (in vitro and in vivo): Negative.
Carcinogenicity IARC	IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.
Carcinogenicity ACGIH	No data available. Animal testing did not show any carcinogenic effects.
Carcinogenicity NTP	No data available. Animal testing did not show any carcinogenic effects.
Carcinogenicity OSHA	No data available. Animal testing did not show any carcinogenic effects.
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.
Specific Target Organ Toxicity - Single Exposure	No effects identified in animal studies.
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.
Aspiration Hazard	No aspiration toxicity classification

Section 12: Ecological Information

Toxicity	NOEC / 96 h / Oncorhynchus mykiss (rainbow trout): 2 100g/l (highest concentration tested) LC50 / 96 h / Oncorhynchus mykiss (rainbow trout): > 2 100g/l NOEC (embryo + 28 days post hatch) / Pimephales promelas (fathead minnow): 1 200g/l (highest concentration tested) NOEC / 28 d / C. riparius: 250 mg/kg Aquatic Exposure Guideline Tadalafil: Drinking Water: 2,5g/l Chronic Exposure of Aquatic Organisms: 200g/l Acute Exposure of Aquatic Organisms: 1 000g/l
Persistence and Degradability	Tadalafil: 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: DT 50: 9 days Degradation in Aquatic Sediments (108-day aerobic incubation): DT 50 from overlying water: 3.8 to 4.6 days DT 50 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
Bio-accumulative Potential	Log Kow: < 4.
Mobility in Soil	No data available (Tadalafil)
Other Adverse Effects	No data available

Section 13: Disposal Considerations

Waste Treatment Methods Product	In accordance with local and nation regulations.
Waste Treatment Methods Packaging	In accordance with local and nation regulations.
Special Precautions Landfill or Incinerations	No data available
Other Information	No data available

Section 14: Transport Information

UN Number	Not dangerous goods.
UN Proper Shipping Name	N/A
Transport Hazard Class(es)	N/A
Packaging Group	N/A
Environmental Hazards	N/A

Section 15: Regulatory Information

No data available.

Section 16: Other Information

Additional Information	N/A
Prepared By	Scarlotte Smith
Revision Date	12/05/2024 09:53

Disclaimer

Letco Medical, LLC believes that the above information is correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. If the product is used as a component in another product, this information may not be applicable. NO WARRANTY OF FITNESS FOR ANY PARTICULAR PURPOSE, WARRANTY OF MERCHANTABILITY OR ANY OTHER WARRANTY, EXPRESSED OR IMPLIED, IS MADE CONCERNING THE INFORMATION PROVIDED ABOVE. Letco Medical shall not be held liable for any loss or damage resulting from handling, storage, use or from contact with the above product.