

SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME	TADALAFIL, USP
PRODUCT CODE	3062
SUPPLIER	MEDISCA Inc. Tel.: 1.800.932.1039 Fax.: 1.855.850.5855 661 Route 3, Unit C, Plattsburgh, NY, 12901 3955 W. Mesa Vista Ave., Unit A-10, Las Vegas, NV, 89118 6641 N. Belt Line Road, Suite 130, Irving, TX, 75063 MEDISCA Pharmaceutique Inc. Tel.: 1.800.665.6334 Fax.: 514.338.1693 4509 Rue Dobrin, St. Laurent, QC, H4R 2L8 21300 Gordon Way, Unit 153/158, Richmond, BC V6W 1M2 MEDISCA Australia PTY LTD Tel.: 1.300.786.392 Fax.: 61.2.9700.9047 Unit 7, Heritage Business Park 5-9 Ricketty Street, Mascot, NSW 2020
EMERGENCY PHONE	CHEMTREC Day or Night Within USA and Canada: 1-800-424-9300 NSW Poisons Information Centre: 131 126
USES	Urological drug

SECTION 2: HAZARDS IDENTIFICATION

GHS CLASSIFICATION	Eye Irritation (Category 2B) Acute Aquatic Toxicity (Category 2)		
PICTOGRAM	Not Applicable		
SIGNAL WORD	Warning		
HAZARD STATEMENT(S)	Causes eye irritation. Toxic to aquatic life. Harmful if swallowed, in contact with skin, or if inhaled. Causes skin irritation.		
AUSTRALIA-ONLY HAZARDS	Not Applicable.		
PRECAUTIONARY STATEMENT(S)	Prevention Response	Wash thoroughly after handling. Avoid release to the environment. Do not eat, drink or smoke when using this product. Wear protective gloves/protective clothing. Avoid breathing dust/fume/gas/mist/ vapors/spray. Use only outdoors or in a well-ventilated area. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention. IF SWALLOWED: Immediately call a poison center or medical professional; Rinse mouth. IF ON SKIN (HAIR): Wash with plenty of water; Call a poison center or medical professional; Take off immediately all contaminated clothing and wash it before reuse. IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a poison center or medical professional.	
	Storage	Not applicable	
	Disposal	Dispose of contents and/or container in accordance with local regulations.	
HMS CLASSIFICATION	Health Hazard	1	Flammability 0

Reactivity

0

Personal Protection

E

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

CHEMICAL NAME	(6R, 12aR)-2,3,6,7,12,12a-Hexahydro-2-methyl-6-(3,4-(methylenedioxy)phenyl) pyrazino(1',2':1,6)pyrido(3,4-b)indole-1,4-dione						
BOTANICAL NAME	Not applicable						
SYNONYM	Not applicable						
CHEMICAL FORMULA	C ₂₂ H ₁₉ N ₃ O ₄						
CAS NUMBER	171596-29-5						
ALTERNATE CAS NUMBER	Not applicable						
MOLECULAR WEIGHT	389.4091						
COMPOSITION	<table border="1"> <thead> <tr> <th>CHEMICAL NAME</th> <th>CAS NUMBER</th> <th>% BY WEIGHT</th> </tr> </thead> <tbody> <tr> <td>TADALAFIL</td> <td>171596-29-5</td> <td>100</td> </tr> </tbody> </table>	CHEMICAL NAME	CAS NUMBER	% BY WEIGHT	TADALAFIL	171596-29-5	100
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TADALAFIL	171596-29-5	100					

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as health hazards and hence require reporting in this section.

NOTES
Chemical family: Indole.

SECTION 4: FIRST-AID MEASURES

IN CASE OF EYE CONTACT	Flush with copious amounts of water for 15 minutes, separating eyelids with fingers. If irritation persists seek medical aid.
IN CASE OF SKIN CONTACT	Wash with soap & water for 15 minutes. If irritation persists seek medical aid.
IF SWALLOWED	Call a physician. Wash out mouth with water. Do not induce vomiting without medical advice.
IF INHALED	Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician
SYMPTOMS AND EFFECTS	Not expected to present a significant hazard under anticipated conditions of normal use.

SECTION 5: FIREFIGHTING MEASURES

SPECIFIC HAZARDS ARISING FROM THE CHEMICAL	Not applicable
FLAMMABLE PROPERTIES	May be combustible at high temperature
HAZARDOUS COMBUSTION PRODUCTS	Under fire conditions, hazardous fumes will be present.
EXTINGUISHING MEDIA	Small fire: dry chemical, CO ₂ or water spray. Large fire: dry chemical, CO ₂ , alcohol resistant foam or water spray. Do not get water inside containers.
PROTECTIVE EQUIPMENT AND 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

Wear respiratory protection. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.

METHODS & MATERIAL FOR CONTAINMENT

On land, sweep or shovel into suitable containers. Minimize generation of dust.

CLEANUP PROCEDURE

Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Wear respirator, chemical safety goggles, rubber boots and heavy rubber gloves. Stop leak if you can do it without risk. Prevent entry into waterways, sewers, basements or confined areas. Shut off all sources of ignition. Evacuate the area. If necessary, employ water fog to disperse the vapors. Absorb the matter with compatible vermiculite or other absorbing material. Place in a suitable container and retain for disposal. Ventilate and clean the affected area. Do not flush into sewerage system or to drains.

SECTION 7: HANDLING AND STORAGE
PRECAUTIONS FOR SAFE HANDLING

Do not inhale. Avoid contact with eyes, skin and clothing. Avoid prolonged or repeated exposure. Wash thoroughly after handling.

STORAGE CONDITIONS

Store in original container, tightly sealed, protected from direct sunlight, in a dry and well-ventilated area, away from incompatible materials. Store in accordance with local regulations. Eliminate all ignition sources. Separate from oxidizing materials. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabelled containers. Use appropriate containment to avoid environmental contamination.

Preserve in well-closed, light-resistant containers. Store at room temperature.

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

Chemical Name: TADALAFIL CAS #: 171596-29-5

	TWA	Ceiling	STEL	REL	IDLH	Remarks
OSHA PEL	N/L	N/L	-	-	-	-
ACGIH TLV	N/L	N/L	N/L	-	-	-
NIOSH	N/L	N/L	N/L	N/L	N/L	-
AIHA WEEL	N/L	N/L	N/L	-	-	-
Safe Work Australia HSIS	N/L	N/L	N/L	-	-	-
HSE	N/L	N/L	N/L	-	-	-

N/L = Not Listed

EXPOSURE GUIDELINES

Consult local authorities for provincial or state exposure limits. Particulates not otherwise regulated, respirable fraction: 5 mg/m³.

PERSONAL PROTECTIVE EQUIPMENT

Eyes: Wear appropriate protective eyeglasses or chemical safety goggles as described by WHMIS or OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166. **Skin:** Wear appropriate gloves to prevent skin exposure. **Clothing:** Wear appropriate protective clothing to minimize contact with skin. **Respirators:** Follow WHMIS or OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced.

SPECIFIC ENGINEERING CONTROLS

Adequate mechanical ventilation. Fumehood, eye wash station, and safety shower.

NOTES

USP: ELV: Industrial: TWA: TWA 0.02 mg/m³.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES
PHYSICAL STATE

Solid

DESCRIPTION	White or almost white powder.				
SOLUBILITY	Freely soluble in dimethyl sulfoxide; slightly soluble in methylene chloride; practically insoluble in water.				
ODOR	Odorless				
FLAMMABILITY	May be combustible at high temperature				
ODOR THRESHOLD	Not available	pH	Not available	MELTING POINT	(302 - 306)°C, (575.6-582.8)°F
BOILING POINT	Not available	FREEZING POINT	(302 - 306)°C, (575.6-582.8)°F	FLASH POINT	Not available
SPECIFIC GRAVITY	Not available	EVAPORATION RATE	Not available	EXPLOSIVE LIMIT	Not available
UPPER FLAMMABLE/ EXPLOSIVE LIMIT(S)	Not available	LOWER FLAMMABLE/ EXPLOSIVE LIMIT(S)	Not available	VAPOR PRESSURE	Not available
VAPOR DENSITY (AIR = 1)	Not available	RELATIVE DENSITY (WATER = 1)	Not available	log P (OCTANOL-WATER)	2.89
AUTO-IGNITION TEMPERATURE	Not available	DECOMPOSITION TEMPERATURE	Not available	VISCOSITY	Not available

SECTION 10: STABILITY AND REACTIVITY

REACTIVITY	Not established
STABILITY	Stable under recommended storage conditions
MATERIALS TO AVOID	Strong oxidants
HAZARDOUS DECOMPOSITION PRODUCTS	Toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides and other gases may occur
HAZARDOUS POLYMERIZATION	Will not occur
POSSIBILITY OF HAZARDOUS REACTION	Not established
CONDITIONS TO AVOID	Moisture, sunlight and extreme temperatures. Light sensitive.

SECTION 11: TOXICOLOGICAL INFORMATION

ACUTE TOXICITY	Oral: Rat: LD50: (mg/kg): > 2000 Dermal: Rabbit: LD50: (mg/kg): > 1000 Inhalation: Rat: LD50: (mg/L/4hr): Not available
SKIN CORROSION/IRRITATION	Based on available data, the classification criteria are not met. Irritancy test: Rabbit: Skin: Slight irritant.
SERIOUS EYE DAMAGE/EYE IRRITATION	Causes eye irritation. Irritancy test: Rabbit: Eye: Slight irritant.
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	Due to lack of data the classification is not possible. Data from germ cell mutagenicity tests were not found.
CARCINOGENICITY	OSHA TADALAFIL is not listed. NTP TADALAFIL is not listed. IARC TADALAFIL is not evaluated. California Proposition 65 This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm.
ADDITIONAL CARCINOGENICITY INFORMATION	Based on available data, the classification criteria are not met. Carcinogenicity study: Mouse: 2 years: 400 mg/kg/day: No evidence of carcinogenicity. Carcinogenicity study: Rat: 2 years: 400 mg/kg/day: No evidence of carcinogenicity.
REPRODUCTIVE TOXICITY	Based on available data, the classification criteria are not met. Fertility study: Human: 6 months: 10 - 20 mg/kg/day: No adverse effects on sperm or testosterone in males. Reproductivity study: Mouse: 1000 mg/kg/day: Not teratogenic, embryotoxic, or fetotoxic. Reproductivity study: Rat: 1000 mg/kg/day: Not teratogenic, embryotoxic, or fetotoxic. Reproductivity study: Rat: 30 mg/kg/day: No developmental adverse effects.
SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE	Based on available data, the classification criteria are not met.
SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE	Based on available data, the classification criteria are not met.
ASPIRATION HAZARDS	Based on available data, the classification criteria are not met.
SIGNS AND SYMPTOMS OF EXPOSURE	Not expected to present a significant hazard under anticipated conditions of normal use. Symptoms related to the physical, chemical, and toxicological characteristics: Phosphodiesterase (PDE) 5 inhibitors: Nausea. Headache. Flu-like symptoms. Indigestion. Nasal congestion. Flushing. Dizziness. Vertigo. Visual disturbances. Insomnia. Anxiety. Muscle pain. Back pain. Leg pain. Prolonged or painful erection in men. Delayed and immediate effects of exposure: Phosphodiesterase (PDE) 5 inhibitors: Rhinitis. Sinusitis. Low blood pressure. Medical conditions aggravated by exposure: Phosphodiesterase (PDE) 5 inhibitors: Kidney impairment. Bleeding disorders. Peptic ulcer. Retinitis pigmentosa. Use of nitrates.
POTENTIAL HEALTH EFFECTS	Inhalation Harmful if inhaled. May cause respiratory tract irritation. Ingestion Harmful if swallowed. Skin Harmful if absorbed through skin. Causes skin irritation. Eyes Causes eye irritation.

SECTION 12: ECOLOGICAL INFORMATION

TOXICITY	EC50: 48 Hr: Crustacea (Daphnia): (mg/L): > 2 LC50: 96 Hr: Fish (Oncorhynchus mykiss): (mg/L): > 2.1 IC50: 72 Hr: Algae: (mg/L): Not available
PERSISTENCE AND DEGRADABILITY	No data is available on the degradability of this product.
BIOACCUMULATIVE POTENTIAL	Log Pow: 2.89.
MOBILITY IN SOIL	Practically insoluble in water.
OTHER ADVERSE EFFECTS	Not available
	This product is not intended to be released into the environment

SECTION 13: DISPOSAL CONSIDERATIONS
WASTE DISPOSAL

Dispose of in accordance with federal / local laws and regulations. Avoid release into the environment.

SECTION 14: TRANSPORT INFORMATION
UNITED STATES & CANADA
UN PROPER SHIPPING NAME

Not dangerous good

UN NUMBER

Not applicable

CLASS

Not applicable

PACKING GROUP

Not applicable

AUSTRALIA
UN PROPER SHIPPING NAME

Not dangerous good

UN NUMBER

Not applicable

CLASS

Not applicable

PACKING GROUP

Not applicable

HAZCHEM

Not applicable

ENVIRONMENTAL HAZARDS

Not available

SPECIAL SHIPPING INFORMATION

Not applicable

SECTION 15: REGULATORY INFORMATION

Chemical Name & CAS	CERCLA 40 CFR Part 302.4	SARA (Title III) 40 CFR Part 372.65	EPA 40 CFR Part 355		Pennsylvania	Right-to-know		California Prop 65
			Appendix A	Appendix B		New Jersey	Massachusetts	
TADALAFIL 171596-29-5	N/L	N/L	N/L	N/L	N/L	N/L	N/L	N/L

N/L = Not Listed; X = Listed

AUSTRALIAN REGULATIONS

Chemical Name & CAS	Poisons and Therapeutic Goods Regulation	Therapeutic Goods Act	Code of Practices - Illicit Drug Precursors
TADALAFIL 171596-29-5	Not Listed	Listed as Schedule 4	Not Listed

SECTION 16: OTHER INFORMATION
REFERENCES

Available upon request

ABBREVIATIONS AND ACRONYMS

CAS – Chemical Abstract Service; **GHS** – Global Harmonized System; **OSHA PEL** – Occupational Safety & Health Administration Permissible Exposure Limits; **TWA** – Time Weighted Average; **HSIS** – Hazardous Substances Information System; **STEL** – Short Term Exposure Limit; **AIHA WEEL** – American Industrial Hygiene Association Workplace Environment Exposure Levels; **LD50** – Lethal Dose, 50%; **IARC** – International Agency for Research on Cancer; **NTP** – National Toxicology Program; **WHMIS** – Workplace Hazardous Materials Information System; **SARA** – Superfund Amendments and Reauthorization Act; **EPA** – Environmental Protection Agency; **CERCLA** – Comprehensive Environmental Response, Compensation, and Liability Act; **HMIS** – Hazardous Materials Information System; **NIOSH** – National Institute for Occupational Safety and Health; **MSHA** - Mine Safety and Health Administration; **ACGIH** - American Conference of Governmental Industrial Hygienists; **IDHL** - Immediately Dangerous to Health or Life; **TLV** – Threshold Limit Value; **HSE** – Health and Safety Executive; **REL** - Recommended Exposure Limit

LAST REVISION

06/2017

SUPERSEDES

Not applicable

DISCLAIMER

This document was created in accordance with OSHA, Safe Work Australia and WHMIS regulations. The above information is believed to be 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. It does not represent any guarantee of the properties of the product. MEDISCA[®] shall not be held liable for any damage resulting from handling or from contact with the above product. Recipients of the product must take responsibility for observing existing laws and regulations.