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
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.

Response
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.

HMIS CLASSIFICATION
Health Hazard 1
Flammability 0
SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>CHEMICAL NAME</th>
<th>(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</th>
</tr>
</thead>
<tbody>
<tr>
<td>BOTANICAL NAME</td>
<td>Not applicable</td>
</tr>
<tr>
<td>SYNONYM</td>
<td>C₂₂H₁₉N₃O₄</td>
</tr>
<tr>
<td>CHEMICAL FORMULA</td>
<td>C₂₂H₁₉N₃O₄</td>
</tr>
<tr>
<td>CAS NUMBER</td>
<td>171596-29-5</td>
</tr>
<tr>
<td>ALTERATE CAS NUMBER</td>
<td>Not applicable</td>
</tr>
<tr>
<td>MOLECULAR WEIGHT</td>
<td>389.4091</td>
</tr>
<tr>
<td>COMPOSITION</td>
<td>TADALAFIL 171596-29-5</td>
</tr>
<tr>
<td></td>
<td>% BY WEIGHT 100</td>
</tr>
</tbody>
</table>

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, CO₂ or water spray. Large fire: dry chemical, CO₂, 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
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

<table>
<thead>
<tr>
<th></th>
<th>TWA</th>
<th>Ceiling</th>
<th>STEL</th>
<th>REL</th>
<th>IDLH</th>
<th>Remarks</th>
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</thead>
<tbody>
<tr>
<td>OSHA PEL</td>
<td>N/L</td>
<td>N/L</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
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<tr>
<td>ACGIH TLV</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>NIOSH</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>-</td>
</tr>
<tr>
<td>AIHA WEEL</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Safe Work Australia HSIS</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>HSE</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

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
SAFETY DATA SHEET

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

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

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.
<table>
<thead>
<tr>
<th><strong>GERM CELL MUTAGENICITY</strong></th>
<th>Due to lack of data the classification is not possible. Data from germ cell mutagenicity tests were not found.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CARCINOGENICITY</strong></td>
<td><strong>OSHA</strong> TADALAFIL is not listed. <strong>NTP</strong> TADALAFIL is not listed. <strong>IARC</strong> TADALAFIL is not evaluated. <strong>California Proposition 65</strong> This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm.</td>
</tr>
<tr>
<td><strong>ADDITIONAL CARCINOGENICITY INFORMATION</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>REPRODUCTIVE TOXICITY</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE</strong></td>
<td>Based on available data, the classification criteria are not met.</td>
</tr>
<tr>
<td><strong>SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE</strong></td>
<td>Based on available data, the classification criteria are not met.</td>
</tr>
<tr>
<td><strong>ASPIRATION HAZARDS</strong></td>
<td>Not expected to present a significant hazard under anticipated conditions of normal use.</td>
</tr>
</tbody>
</table>

### Potential Health Effects

<table>
<thead>
<tr>
<th><strong>Inhalation</strong></th>
<th>Harmful if inhaled. May cause respiratory tract irritation.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ingestion</strong></td>
<td>Harmful if swallowed.</td>
</tr>
<tr>
<td><strong>Skin</strong></td>
<td>Harmful if absorbed through skin. Causes skin irritation.</td>
</tr>
<tr>
<td><strong>Eyes</strong></td>
<td>Causes eye irritation.</td>
</tr>
</tbody>
</table>

### Section 12: Ecological Information

<table>
<thead>
<tr>
<th><strong>TOXICITY</strong></th>
<th>EC50: 48 Hr: Crustacea (Daphnia): (mg/L): &gt; 2</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>LC50: 96 Hr: Fish (Oncorhynchus mykiss): (mg/L): &gt; 2.1</td>
</tr>
<tr>
<td></td>
<td>IC50: 72 Hr: Algae: (mg/L): Not available</td>
</tr>
<tr>
<td><strong>PERSISTENCE AND DEGRADABILITY</strong></td>
<td>No data is available on the degradability of this product.</td>
</tr>
<tr>
<td><strong>BIOACCUMULATIVE POTENTIAL</strong></td>
<td>Log Pow: 2.89.</td>
</tr>
<tr>
<td><strong>MOBILITY IN SOIL</strong></td>
<td>Practically insoluble in water.</td>
</tr>
<tr>
<td><strong>OTHER ADVERSE EFFECTS</strong></td>
<td>Not available</td>
</tr>
</tbody>
</table>

This product is not intended to be released into the environment
SAFETY DATA SHEET

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

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>TADALAFIL 171596-29-5</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
<td>N/L</td>
</tr>
</tbody>
</table>

N/L = Not Listed; X = Listed

AUSTRALIAN REGULATIONS

<table>
<thead>
<tr>
<th>Chemical Name &amp; CAS</th>
<th>Poisons and Therapeutic Goods Regulation</th>
<th>Therapeutic Goods Act</th>
<th>Code of Practices - Illicit Drug Precursors</th>
</tr>
</thead>
<tbody>
<tr>
<td>TADALAFIL 171596-29-5</td>
<td>Not Listed</td>
<td>Listed as Schedule 4</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

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.