SAFETY DATA SHEET

Tadliq® (Tadalafil) Oral Suspension, 4 mg/mL

SDS DATE: 14-Jan-2025

SECTION 1: IDENTIFICATION

PRODUCT NAME: Tadliq® (Tadalafil) Oral Suspension, 4 mg/mL
SYNONYMS: Tadalafil Oral Suspension, 4 mg/mL
NDC Number: 46287-045-15
MANUFACTURER: CMP Pharma, Inc.
ADDRESS: PO Box 147
8026 East Marlboro Road
Farmville, NC 27828

BUSINESS PHONE: 1-800-227-6637

CHEMICAL NAME (for active ingredient): 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)-
CHEMICAL FORMULA (for active ingredient): $C_{22}H_{19}N_3O_4$
PHARMACOLOGICAL PROPERTIES (for active ingredient): Calcium Channel Blocker

PRODUCT USE: Treatment of pulmonary arterial hypertension

SECTION 2: HAZARD(S) IDENTIFICATION

HEALTH HAZARDS: Do not use tadalafil in patients who are using any form of organic nitrate, either regularly or intermittently. Tadalafil potentiates the hypotensive effect of nitrates. This potentiation is thought to result from the combined effects of nitrates and tadalafil on the nitric oxide/cGMP pathway. Do not use tadalafil in patients who are using a GC stimulator, such as riociguat. Tadalafil may potentiate the hypotensive effects of GC stimulators.

SIGNAL WORD: None

HAZARD SYMBOLS: None

PRECAUTIONARY STATEMENTS:
Do not handle until all safety precautions have been read and understood. Use personal protective equipment as required. Wash hands and face thoroughly after handling. Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do so. Immediately call a poison control center or doctor/physician.

HAZARDS NOT OTHERWISE CLASSIFIED: None classified.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

INGREDIENT:	CAS NO.	Amount
Tadalafil USP	171596-29-5	0.4% w/v

*Product also contains citric acid monohydrate, frozen peppermint flavor, glycerin, polysorbate 80, purified water, simethicone emulsion, sodium benzoate, sucralose powder, trisodium citrate dehydrate, and xanthan gum.

SECTION 4: FIRST AID MEASURES

EYE CONTACT: Flush with copious amounts of water for at least 15 minutes. Hold eyelids away from eyeball to ensure thorough rinsing. Irrigate each eye continuously with normal saline during transport. Seek medical attention immediately.

SKIN CONTACT: Wash the affected area with plenty of warm water and soap. If irritation, redness, or rash persists, seek medical attention.

INGESTION: Do not induce vomiting. Wash out mouth with copious amounts of water. Seek medical attention immediately.

INHALATION: Remove affected person to fresh air and keep patient at rest. Seek medical attention immediately.

MOST IMPORTANT SYMPTOMS/EFFECTS

May cause headache and flushing. Pre-existing medial conditions which may be aggravated by exposure include individuals on nitrate or alpha blocker therapy.

NOTES TO PHYSICIANS OR FIRST AID PROVIDERS:

None

SECTION 5: FIRE-FIGHTING MEASURES

SUITABLE EXTINGUISHING MEDIA:	Water spray, dry chemical, carbon dioxide, or foam as appropriate for surrounding fire and materials.
UNSUITABLE EXTINGUISHING MEDIA:	None known.
UNUSUAL FIRE AND EXPLOSION HAZARDS:	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.
SPECIAL FIRE FIGHTING PROCEDURES:	Evacuate personnel to a safe area. Wear breathing apoparatus and personal protective equipment to prevent contact with skin and eyes.
PROTECTIVE MEASURES:	Prevent runoff from fire control or dilution from entering streams, sewers, or drinking water supply.
MEASURES FOR ENVIRONMENTAL PROTECTIONS:	None known.

SECTION 6: ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS:	Non-essential personnel should be evacuated from the affected area. Spills should be cleaned up in a manner that minimizes exposure to personnel. Personnel involved in the cleanup of spills should wear the appropriate gloves, eye protection, and protective coveralls. Minimize exposure.
METHODS/MATERIALS USED FOR CONTAINMENT & CLEANING:	This material is not known to possess additional hazards when spilled beyond those of other non-hazardous solids.
Environmental Precautions:	Place waste in an appropriately labeled, sealed container for disposal. For large spills, prevent entry into waterways, sewers, or surface draining systems.

SECTION 7: HANDLING AND STORAGE

HANDLING PRECAUTIONS:	No special control measure required for the normal handling of this product.
STORAGE PRECAUTIONS:	Store as directed by product packaging that is labeled in accordance with OSHA's Hazard Communication Standard [29CFR 1910.1200]. Keep this drug out of the reach of children.
CONDITIONS FOR SAFE STORAGE:	Store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F). See USP Controlled Room Temperature.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

EXPOSURE LIMITS/GUIDELINES:

Component Name	Type	Value
Tadalafil	TWA (12 hours)	13 µg/m³
	TWA (8 hours)	20 µg/m³

ENGINEERING CONTROLS: Open handling is not recommended. Use appropriate control measures such as fume hood, ventilated enclosure, isolator. The use of local ventilation is recommended to control emissions near the source. Provide mechanical ventilation for confined spaces. If user operations generate aerosols, use ventilation to keep exposure to airborne contaminants below the exposure limit.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

EYE PROTECTION: Wear appropriate chemical safety goggles, safety glasses, or face shield as described by OSHA's eye and face protection regulations in 29 CFR 1910.133. Have eyewash stations available where eye contact can occur.

SKIN PROTECTION: Avoid unintended skin contact. Wear gloves impervious to conditions of use. A safety shower should be located in the work area.

RESPIRATORY PROTECTION: If exposure limits are exceeded, approved respiratory protection should be worn. Seek professional assistance for proper selection of respiratory protection.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE/ODOR: This product is a white to off white suspension with a peppermint odor.
ODOR THRESHOLD: No data available.

FLASH POINT:	Not established.	**% VOLATILE:**	Not established.
AUTOIGNITION TEMP:	Not established.	**VISCOSITY:**	Not established.
BOILING POINT:	Not established.	**UPPER FLAMMABILITY LIMIT:**	Not established
MELTING POINT:	Not established.	**Octanol/H2O PART. COEFFICIENT:**	Not established.
VAPOR PRESSURE (mmHg):	Not established.	**POUR POINT:**	Not established.
EVAPORATION RATE (H2O = 1):	Not established.	**% SOLUBILITY IN WATER:**	Not established.
VAPOR DENSITY (AIR = 1):	Not established.	**pH:**	4.5 – 5.0
LOWER FLAMMABILITY LIMIT:	Not established.		

SECTION 10: STABILITY AND REACTIVITY

REACTIVITY: Stable under normal conditions and storage. Does not react with water.

POSSIBILITY OF HAZARDOUS REACTIONS: Hazardous polymerization does not occur.

CONDITIONS TO AVOID: None known.

INCOMPATIBLE MATERIALS: Strong oxidizing agents.

HAZARDOUS DECOMPOSITION PRODUCTS: Hazardous decomposition products formed under fire conditions.

SECTION 11: TOXICOLOGICAL INFORMATION

INFORMATION ON LIKELY ROUTES OF EXPOSURE:

INGESTION:	No deaths or toxicity.
INHALATION:	No data available.
SKIN CONTACT:	Slight irritant.
EYE CONTACT:	Avoid contact with eyes. May cause irritation of the eyes.

SIGNS AND SYMPTOMS OF OVEREXPOSURE:
Eye irritation, abdominal pain, dizziness, flushing, heart palpitations, and swelling.

ACUTE TOXICITY VALUES:	LD 50 for active ingredient (oral, rat) > 2000 mg/kg
	LD 50 for active ingredient (dermal, rabbit) > 1000 mg/kg
Carcinogenity:	Not listed by OSHA, NTP, or IARC.

SECTION 12: ECOLOGICAL INFORMATION

ECOLOGICAL INFORMATION:
This product has not been tested for persistence, biodegradability, bioconcentration, soil absorption, or mobility. Care should be taken to avoid environmental release.

ECOTOXICITY INFORMATION:
Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

SECTION 13: DISPOSAL CONSIDERATIONS

WASTE DISPOSAL METHOD:
It is the responsibility of the generator to determine at the time of disposal whether the product meets the criteria of a hazardous waste per regulations of the area in which the waste is generated and/or disposed of. Waste disposal must be in accordance with all local, state, and federal regulations. Wear proper protective equipment when handling waste materials.

WASTE DISPOSAL CONTAINERS:
Waste materials must be placed in and shipped in appropriate poly or metal waste pails or drums. Permeable cardboard containers are not appropriate and should not be used. Ensure that any required marking or labeling of the containers is done in accordance with all applicable regulations.

SECTION 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**

SECTION 15: REGULATORY INFORMATION

U.S. FEDERAL REGULATIONS

TOXIC SUBSTANCE CONTROL ACT (TSCA):
All components of this product are included on the TSCA inventory.

CLEAN WATER ACT (CWA):
There are no ingredients in this mixture listed in the Clean Water Act.

CLEAN AIR ACT (CAA):
There are no ingredients in this mixture listed under the Clean Air Act.

SARA TITLE III (SUPERFUND AMENDMENTS AND REAUTHORIZATION ACT):
There are no ingredients in this mixture listed under SARA.

STATE REGULATIONS:
Complies with OSHA standards. 29CFR1910.

INTERNATIONAL REGULATIONS:

CANADIAN ENVIRONMENTAL PROTECTION ACT:
Listed

CANADIAN WORKPLACE HAZARDOUS MATERIALS INFORMATION SYSTEMS (WHMIS):
Listed

EUROPEAN INVENTORY OF EXISTING CHEMICALS (EINECS):
Listed

EU CLASSIFICATION:
European labeling in accordance with EC directives.

EU RISK (R) AND SAFETY (S) PHRASES (OCCUPATIONAL EXPOSURE):

R38	Irritating to skin
R43	May cause sensitization by skin contact
R61	May cause harm to unborn child
S2	Keep out of the reach of children
S36/27	Wear suitable protective clothing and gloves

SECTION 16: OTHER INFORMATION

CREATION DATE: 18Aug2022 **REVISION DATE:** 14Jan2025

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