SAFETY DATA SHEET

Sildenafil for Oral Suspension 10 mg/mL

EMERGENCY OVERVIEW

Sildenafil for Oral Suspension contains an active drug substance Sildenafil Citrate USP and pharmaceutical excipients generally considered safe, non-toxic and non-hazardous. The quantities of the excipients used in the product are well within the IID (Inactive Ingredient Database) limits prescribed by USFDA for oral route.

WARNING: Accidental ingestion of large amounts may be harmful.

Section 1. Identification of the substance

Identification of the product

Product name	**:**	Sildenafil for Oral Suspension
Potencies	**:**	10 mg/mL
Chemical Name	**:**	1-[[3-(6,7-dihydro-1-methyl-7-oxo-3-propyl-1H-pyrazolo [4,3-d]pyrimidin-5-yl)-4-ethoxyphenyl]sulfonyl]-4-methylpiperazine citrate.
Therapeutic Category	**:**	Phosphodiesterase-5 (PDE5) inhibitor.
Product Use	**:**	Treatment of pulmonary arterial hypertension (PAH) (WHO Group I) in adults to improve exercise ability and delay clinical worsening.
Marketed by	**:**	**Ajanta Pharma USA Inc**. Bridgewater, NJ 08807. Made in India
Contact Information	**:**	855-664-7744

Section 2. Health hazards information

Potential Health Effects **:**

Inhalation: Not expected to be hazardous in final pharmaceutical form.

Eye Contact: Not expected to be hazardous in final pharmaceutical form.

Skin Contact: Not expected to be hazardous in final pharmaceutical form.

Ingestion: Health injuries are not known or expected under normal use. Exposures above clinical dosage could result in adverse effects. Minor occupational exposures are not expected to be harmful.

Effects of Overexposure : The potential for exposure is reduced in finished pharmaceutical dosage form.

Section 3. Composition / information on ingredients

Active ingredient	Exposure Limit	CAS No.
Sildenafil Citrate USP	TWA-8 Hr: 350µg/m^3	171599-83-0

Inactive ingredients: The inactive ingredients include sorbitol, citric acid anhydrous, sucralose, sodium citrate dihydrate, xanthan gum, titanium dioxide, sodium benzoate, colloidal silicon dioxide and grape flavor. Composition of grape flavor: Maize maltodextrin and flavorings.

Section 4. First aid measures

The product in the final dosage form (Oral Suspension) does not pose a problem of exposure to active drug substance and should not cause inhalation, skin and eye irritation problem. However, in case of exposure:

Eye Contact : Immediately flush eyes with water for at least 15 minutes. Get medical attention.

Skin Contact : Remove contaminated clothing. Immediately wash skin with soap and plenty of water for at least 15 minutes. Get medical attention if symptoms occur. Wash clothing before reuse.

Ingestion : Never give anything by mouth to an unconscious person. Wash out mouth with water provided person is conscious. Get medical attention. DO NOT induce vomiting unless directed to do so by medical personnel.

Inhalation : Remove to fresh air and keep patient at rest. If not breathing, give artificial respiration or oxygen by trained personnel. Get immediate medical attention immediately.

Medical Treatment : Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information center. Protect the patient's airway and support ventilation and perfusion. Meticulously monitor and maintain, within acceptable limits, the patient's vital signs, blood gases, serum electrolytes, etc.

Over dosage : In studies with healthy volunteers when dosed up to 800 mg in a single dose, showed similar adverse event to those seen at lower doses but incidence rates and severities were increased. In cases of overdose, standard supportive measures should be adopted as required. Renal dialysis is not expected to accelerate clearance as sildenafil is highly bound to plasma proteins and it is not eliminated in the urine.

Section 5. Fire-fighting measures

Flash Point	:	Not available.
Extinguishing Media	:	Extinguish fires with CO2, extinguishing powder, foam, or water.
General Fire Hazards/ Hazardous Combustible Products	:	Formation of toxic gases is possible during heating or fire.
Special Fire Fighting Procedures	:	Wear self-contained breathing apparatus pressure-demand (NIOSH approved or equivalent), and full protective gear to prevent contact with skin and eyes.

Section 6. Accidental release measures

Personal Precautions	:	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
Environmental Protections	:	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
Clean-up Methods	:	Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. Wipe up with a damp cloth or a filtered vacuum to clean spills of dry solids and place in container for disposal. Clean spill area thoroughly. Prevent discharge to drains.
Additional Consideration for Large Spills	:	Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

Section 7. Handling and storage

Handling	:	No special control measures required for the normal handling of this product. Normal room ventilation is expected to be adequate for routine handling of this product. Minimize dust generation and accumulation. Avoid breathing dust. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions

of the material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Storage : Recommended storage for sildenafil for oral suspension: Store below 30°C (86°F) in the original package in order to protect from moisture.
Reconstituted Oral Suspension: Store below 30°C (86°F) or in refrigerator at 2°C to 8°C (36° F to 46°F). Do not freeze. The shelf-life of the reconstituted oral suspension is 60 days. Any remaining oral suspension should be discarded 60 days after reconstitution.

Section 8. Exposure controls/personal protection

Exposure Limits : OEL TWA-8 Hr: 350µg/m^3

Engineering Controls : Engineering controls should be used as the primary means to control exposures. In laboratory, medical or industrial setting use appropriate ventilation. Keep airborne contamination levels below the exposure limits.

Respiratory Protection : For consumer use, no unusual precaution are necessary. However, for handling bottles, in laboratory, medical or industrial setting use NIOSH/MSHA approved respirators for protection if necessary. Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a half mask, P3 filter).

Personal Protection : For consumer use, no unusual precaution are necessary. However, for handling bottles in laboratory, medical or industrial setting use gloves as recommended.

Recommended Facilities : None

Section 9. Physical and chemical properties

Appearance : Sildenafil powder for oral suspension is supplied in amber glass bottles enclosed in a gusset pouch individually packed in a carton containing a 2 mL oral dosing syringe (with 0.5 mL and 2 mL dose markings) and a press-in bottle adaptor. Each bottle contains off-white to light yellow powders containing 1.57 g of sildenafil citrate, USP (equivalent to 1.12 g sildenafil). Following reconstitution, the volume of the oral suspension is 112 mL (10 mg sildenafil/mL) which is a off-white to light yellow colored, grape flavored suspension.

Sildenafil for Oral Suspension 10 mg/mL		
Package Configuration	Strength	NDC
Bottle with child-resistant closure	10 mg/mL (when reconstituted)	27241-175-29

Other Information : Sildenafil citrate USP is a white to off-white crystalline powder with a solubility of 3.5 mg/mL in water and a molecular weight of 666.7.

Section 10. Stability and reactivity

Stability : Stable under normal conditions of use.
Incompatibility : Incompatible with strong oxidizing agent.
Hazardous Decomposition : Data not available.
Conditions to Avoid : Incompatible materials, strong oxidants.

Section 11. Toxicological information

Acute toxicity : Rat Oral LDmin. 300-500 mg/kg
Mouse Oral LDmin. 500-1000 mg/kg
Rat Dermal LD50 > 2000 mg/kg
Carcinogenesis : None of the components of this product are suspected to be a carcinogen.
Genetic Toxicity : When processed and used as directed, this product is not expected to produce toxic effects in humans.
Impairment of Fertility : Based on available data, the classification criteria are not met.

Section 12. Ecological information

Eco toxicity of drug substance : In the environment, the active ingredient in this formulation is expected to remain in water or migrate through the soil to groundwater.

In the finished product form	**:**	There is no potential for air borne contamination since the drug substance is in consolidated form as powder.

Section 13. Disposal Consideration

Waste Disposal Considerations: Dispose the material according to federal, state and local disposal regulations or company operating procedures. Disposal by incineration is recommended. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

Section 14. Transport information

This product is not subject to the regulations for the safe transport of hazardous chemicals

DOT: Not regulated for transport of dangerous goods.
IATA: Not regulated for transport of dangerous goods
IMDG: Not regulated for transport of dangerous goods

Section 15. Regulatory information

DEA: Not Available.
FDA: Sildenafil for Oral Suspension 10 mg/mL is an approved prescription medication.

Section 16. Disclaimer

The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

Ajanta shall not be held liable for any damage resulting from handling or from contact with the above product.

Date: April 07, 2022

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