

SAFETY DATA SHEET

Section 1: Identification	
Material	Voriconazole Powder for Oral Suspension, 40mg/mL
Recommended use	Pharmaceutical product used as Antifungal agent
Manufacturer	Annora Pharma Private Limited, Survey No. 261, Annaram Village, Gummadidala Mandal, Sanga Reddy, Telangana 502313, India (IND)
Distributor	Camber Pharmaceuticals, Inc. , Piscataway, NJ 08854
Section 2: Hazard(s) Identification	
Precautionary statements	P202 - Do not handle until all safety precautions have been read and understood P260 - Do not breathe dust/fume/gas/mist/vapors/spray P281 - Use personal protective equipment as required P308 + P313 - IF exposed or concerned: Get medical attention/advice P405 - Store locked up P501 - Dispose of contents/container in accordance with all local and national regulations
Other hazards	An Occupational Exposure Value has been established for one or more of the ingredients.
Section 3: Composition/Information on Ingredients	
Ingredients	CAS
Voriconazole	137234-62-9
Sucrose	57-50-1
Trisodium citrate	6132-04-3
Citric acid	77-92-9
Silicon dioxide	112945-52-5
Xanthan gum	11138-66-2
Sodium benzoate	532-32-1
Titanium Dioxide	13463-67-7
Natural Orange Flavour	NA

Section 4: First-Aid Measures	
Description of First Aid Measures	
First-aid Measures After Eye Contact:	Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
First-aid Measures After Skin Contact:	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
First-aid Measures After Ingestion:	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.
First-aid Measures After Inhalation:	Remove to fresh air and keep patient at rest. Seek medical attention immediately
Section 5: Fire-Fighting Measures	
Extinguishing Media	
Suitable Extinguishing Media:	Use carbon dioxide, dry chemical, or water spray.
Special hazards arising from the substance or mixture	Carbon monoxide, carbon dioxide, nitrogen oxides and fluorine-containing compounds.
Precautionary Measures Fire:	Wear appropriate protective equipment, including self-contained breathing apparatus.
Section 6: Accidental Release Measures	
Personal Precautions, Protective Equipment and Emergency Procedures	
General Measures:	Personnel involved in clean-up should wear appropriate personal protective equipment. Minimize exposure.
Environmental Precautions	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
Methods for Cleaning Up:	Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.
Section 7: Handling and Storage	
Precautions for Safe Handling	

Additional Hazards When Processed	Minimize dust generation and accumulation. Avoid breathing dust. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment. Wash thoroughly after handling. Releases to the environment should be avoided. Refer to Section 12 - Ecological Information, for information on potential effects on the environment. 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 this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.
Conditions for Safe Storage, Including any Incompatibilities	
Storage Temperature:	Store at 2°- 8°C (36°- 46° F) before reconstitution. The reconstituted suspension should be stored at 15°- 30°C (59°- 86°F) Do not refrigerate or freeze. Keep the container tightly closed.
Specific End Use(s)	Pharmaceutical drug product
Section 8: Exposure Controls/Personal Protection	
Exposure Controls	
Appropriate Engineering Controls:	Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.
Personal Protective Equipment	
Hand Protection	Protective gloves.
Eye Protection	Safety goggles
Skin and Body Protection	Impervious clothing
Respiratory Protection	Suitable respirator.
Environmental Exposure Controls	Keep the product away from drains, water courses or the soil. Clean spillages in a safe way as soon as possible.
Section 9: Physical and Chemical Properties	
Physical Form	Powder

Appearance	<p>Voriconazole Powder for Oral Suspension, 40mg/mL are supplied as:</p> <p>Before Reconstitution - White to off white powder</p> <p>After Reconstitution - White to off white orange flavored suspension</p> <p>100 mL HDPE bottle NDC: 31722-266-31</p>
Section 10: Stability and Reactivity	
Reactivity:	No data available.
Chemical Stability:	Stable under normal conditions of use.
Possibility of Hazardous Reactions:	
Oxidizing Properties:	No data available
Conditions to Avoid:	Fine particles (such as dust and mists) may fuel fires/explosions.
Incompatible Materials:	As a precautionary measure, keep away from strong oxidizers
Hazardous Decomposition Products:	No data available.
Section 11: Toxicological Information	
Acute Toxicity: (Species, Route, End Point, Dose)	<p>Voriconazole Rat/Mouse Oral LD50 < 300 mg/kg Rat/Mouse Oral LDmin. > 100mg/kg Rat IV LD50 > 100mg/kg Rat Dermal LD50 > 2000mg/kg</p> <p>Titanium dioxide Rat Oral LD50 > 7500 mg/kg Rat Subcutaneous LD50 50 mg/kg</p> <p>Xanthan gum Rat Oral LD50 > 5000 mg/kg</p> <p>Sodium benzoate Rat Oral LD50 4,070 mg/kg Mouse Oral LD50 1600mg/kg</p>

<p>Acute Toxicity: (Species, Route, End Point, Dose)</p> <p>Irritation / Sensitization: Study Type, Species, Severity)</p> <p>Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)</p>	<p>Citric acid, anhydrous Rat Oral LD50 3000 mg/kg</p> <p>Sucrose Rat Oral LD50 29.7 g/kg</p> <p>Voriconazole Skin Irritation Rabbit Non-irritating Skin Sensitization - GPMT Guinea Pig Negative Eye Irritation Rabbit Minimal</p> <p>Citric acid, anhydrous Eye Irritation Rabbit Severe Skin Irritation Rabbit Mild</p> <p>Voriconazole 1 Month(s) Rat Oral 30 mg/kg/day NOAEL Liver 6 Month(s) Rat Oral 3 mg/kg/day NOAEL Liver, Kidney 12 Month(s) Dog Oral 8 mg/kg/day NOAEL Liver 6 Month(s) Rat Intravenous 10 mg/kg/day NOAEL Liver 6 Month(s) Dog Oral 6 mg/kg/day NOAEL Liver Blood, Ureter, Bladder</p>
<p>Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))</p> <p>Genetic Toxicity: Study Type, Cell Type/Organism, Result)</p>	<p>Voriconazole Reproductive & Fertility Rat Oral 3 mg/kg/day NOAEL Fetotoxicity Embryo / Fetal Development Rat Oral 10 mg/kg/day LOAEL Teratogenic</p> <p>Sodium benzoate Embryo / Fetal Development Rat Oral 44 g/kg LOEL Developmental toxicity</p> <p>Voriconazole Bacterial Mutagenicity (Ames) Bacteria Negative In Vitro Human Lymphocytes Equivocal In Vivo Micronucleus Mouse Negative</p>
<p>Section 12: Ecological Information</p>	
<p>Toxicity</p>	

<p>Aquatic Toxicity: (Species, Method, End Point, Duration, Result)</p> <p>Aquatic Toxicity Comments</p> <p>Bacterial Inhibition</p> <p>Chronic Aquatic Toxicity: (Species, Method, Duration, Endpoint, Result, Adverse Endpoint)</p>	<p>Voriconazole Mysidopsis bahia (Mysid Shrimp) NPDES LC50 48 Hours 62 mg/L Red Algae IC50 73 mg/L Skeletonema costatum (Marine Diatom) NPDES IC-50 48 Hours 74.7 mg/L Green Algae OECD EbC50/72hr (OECD) EC50 72 Hours > 97 mg/L Oncorhynchus mykiss (Rainbow Trout) OECD LC50 96 Hours 110 mg/L</p> <p>A greater than symbol (>) indicates that aquatic toxicity was not observed at the maximum dose tested.</p> <p>Voriconazole Activated sludge OECD EC50 > 810 mg/L Polytox MIC > 100 mg/L</p> <p>Voriconazole Daphnia magna (Water Flea) OECD 21 Day(s) NOEC > 1 mg/L Pimephales promelas (Fathead Minnow) OECD 32 Day(s) NOEC 1.2 mg/L Chironomus riparius (Sediment-Dwelling Midges) OECD 28 Day(s) NOEC 100 mg/L</p>
<p>Persistence and degradability</p>	<p>Voriconazole OECD Activated sludge Ultimate (CO2 Evolution) -0.24% After 28 Day(s) Not Ready</p>
<p>Bio-accumulative Potential:</p>	<p>Voriconazole Measured 7 Log P 1.75</p>
<p>Mobility in Soil:</p>	<p>No data available</p>
<p>Section 13: Disposal Considerations</p>	
<p>Waste Treatment Methods:</p>	<p>Dispose substance in accordance with prevailing country, federal, state and local regulations.</p>
<p>Section 14: Transport Information</p>	
<p>In Accordance with DOT</p>	<p>Not dangerous goods</p>
<p>In Accordance with IATA</p>	<p>Not dangerous goods</p>

In Accordance with IMDG	Not dangerous goods
Section 15: Regulatory Information	
California Prop. 65 Components:	Not Listed
SARA 313 Hazards:	Not Listed
Section 16: Other Information	
<p>Issue Date : 04-11-2025</p> <p>Version: 00</p> <p>Further information</p> <p>Revision date: New issue</p> <p>Revision note: New issue</p> <p>The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. 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.</p> <p>Annora Pharma Private Limited shall not be held liable for any damage resulting from handling or from contact with the above product. Annora Pharma Private Limited reserves the right to revise this SDS.</p>	