

**SAFETY DATA SHEET**

Section 1: Identification	
<b>Material</b>	Sirolimus Oral Solution 1mg/mL
<b>Recommended use</b>	Pharmaceutical. Use only as directed.
<b>Manufacturer</b>	Annora Pharma Private Limited, Survey No. 261, Annaram Village, Gummadidala Mandal, Sangareddy, Telangana 502313, India.
<b>Distributor</b>	<b>Camber Pharmaceuticals, Inc.</b> , Piscataway, NJ 08854
Section 2: Hazard(s) Identification	
<b>Hazard Statements</b>	May damage fertility. May damage the unborn child Very toxic to aquatic life Very toxic to aquatic life with long lasting effects
<b>Precautionary Statements</b>	Obtain special instructions before use Use personal protective equipment as required IF exposed or concerned: Get medical attention/advice Store locked up Avoid release to the environment Collect spillage Dispose of contents/container in accordance with all local and national regulations
<b>Other Hazards</b>	An Occupational Exposure Value has been established for one or more of the ingredients
<b>Note</b>	This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. your needs may vary depending upon the potential for exposure in your workplace.
Section 3: Composition/Information on Ingredients	
<b>Ingredients</b>	<b>CAS</b>
Sirolimus	53123-88-9
Phosal 50PG	774594-96-6
Polysorbate 80 USP-NF	9005-65-6
Section 4: First-Aid Measures	
<b>Eye Contact</b>	Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
<b>Skin Contact</b>	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
<b>Ingestion</b>	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.
<b>Inhalation</b>	Remove to fresh air and keep patient at rest. Seek medical attention immediately.

<b>Most Important Symptoms and Effects, Both Acute and Delayed</b>	
<b>Symptoms and Effects of Exposure:</b>	For information on potential signs and symptoms of exposure, See Section 2- Hazards Identification and/or Section 11- Toxicological Information
<b>Medical Conditions Aggravated by Exposure</b>	None known
<b>Indication of the Immediate Medical Attention and Special Treatment Needed</b>	
<b>Notes to Physician</b>	None
<b>Section 5: Fire-Fighting Measures</b>	
<b>Extinguishing Media</b>	Extinguish fires with CO <sub>2</sub> , extinguishing powder, foam, or water
<b>Special Hazards Arising from the Substance or Mixture</b>	
<b>Hazardous Combustion Products</b>	Formation of toxic gases is possible during heating or fire
<b>Fire / Explosion Hazards</b>	Fine particles (such as dust and mists) may fuel fires/explosions
<b>Advice for Fire-Fighters</b>	During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus
<b>Section 6: Accidental Release Measures</b>	
<b>Personal Precautions, Protective Equipment and Emergency Procedures</b>	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure
<b>Environmental Precautions</b>	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release
<b>Methods and Material for Containment and Cleaning Up</b>	
<b>Measures for Cleaning / Collecting:</b>	Contain the source of the spill or leak. Absorb spills with non-combustible absorbent material and transfer into a labeled container for disposal. Clean spill area thoroughly.
<b>Additional Consideration for Large Spills</b>	Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Cleanup operations should only be undertaken by trained personnel.
<b>Section 7: Handling and Storage</b>	
<b>Precautions for Safe Handling</b>	Restrict access to work area. Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). 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. It is recommended that all operations be fully enclosed and no air recirculated.
<b>Conditions for Safe Storage, Including any Incompatibilities</b>	
<b>Storage Conditions</b>	Store as directed by product packaging
<b>Specific end use(s)</b>	No data available

<b>Section 8: Exposure Controls/Personal Protection</b>	
The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.	
<b>Engineering Controls</b>	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.
<b>Personal Protective Equipment</b>	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes
<b>Hands</b>	Impervious disposable gloves (e.g. Nitrile, etc.) (double recommended) if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)
<b>Eyes</b>	Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)
<b>Skin</b>	Impervious disposable protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)
<b>Respiratory protection</b>	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 full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent.)
<b>Section 9: Physical and Chemical Properties</b>	
<b>Physical Form</b>	Solution
<b>Colour</b>	Pale Yellow to Yellow
<b>Appearance</b>	Each sirolimus oral solution carton, NDC 31722-316-31 contains one 2 oz (60 mL fill) amber glass bottle of sirolimus (concentration of 1 mg/mL), one oral syringe adapter for fitting into the neck of the bottle, sufficient disposable oral syringes (amber color) and caps for daily dosing, and a carrying case.
<b>Section 10: Stability and Reactivity</b>	
<b>Reactivity</b>	No data available

<b>Chemical Stability</b>	Stable under normal conditions of use
<b>Possibility of Hazardous Reactions</b>	
<b>Oxidizing Properties</b>	No data available
<b>Conditions to Avoid</b>	Fine particles (such as dust and mists) may fuel fires/explosions
<b>Incompatible Materials</b>	As a precautionary measure, keep away from strong oxidizers
<b>Hazardous Decomposition</b>	No data available
<b>Section 11: Toxicological Information</b>	
<b>Information on Toxicological Effects</b>	
<b>General Information</b>	The information included in this section describes the potential hazards of the individual ingredients
<b>Known Clinical Effects</b>	Adverse effects associated with therapeutic use include hypersensitivity reactions, nausea, weakness, skin rash, weight loss, inflammation of the mouth (stomatitis), itching sensation (pruritus), decreased red blood cell count (anemia), decreased white blood cells (leukopenia).
<b><u>Acute Toxicity: (Species, Route, End Point, Dose)</u></b>	
<b>Sirolimus</b>	
Mouse Oral LD50 > 2500 mg/kg	
Rat Oral LD50 > 800mg/kg	
<b>Polysorbate 80</b>	
Rat Oral LD50 25 g/kg	
<b>Acute Toxicity Comments :</b> A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.	
<b><u>Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)</u></b>	
<b>Sirolimus</b>	
Monkey No route specified 0.05 mg/kg/day NOAEL Lymphoid tissue, Spleen, Thymus, Gastrointestinal System	
<b><u>Reproduction &amp; Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))</u></b>	
<b>Sirolimus</b>	
Reproductive & Fertility Rat No route specified 0.1 mg/kg/day NOAEL Embryotoxicity, Fetotoxicity	
<b><u>Genetic Toxicity: (Study Type, Cell Type/Organism, Result)</u></b>	
<b>Sirolimus</b>	
In Vitro Bacterial Mutagenicity (Ames) Salmonella, E. coli Negative	
In Vitro Chromosome Aberration Chinese Hamster Ovary (CHO) cells Negative	
In Vitro Forward Mutation Assay Mouse Lymphoma Negative	
In Vivo Micronucleus Bone Marrow Negative	
<b><u>Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))</u></b>	
<b>Sirolimus</b>	
86 Week(s) Mouse No route specified 6 mg/kg/day LOAEL Tumors, Lymphatic system	
104 Week(s) Rat No route specified 0.2 mg/kg/day LOAEL Male reproductive system, Tumors	
<b>Carcinogen Status:</b> Carcinogenicity of the mixture has not been determined. Alcohol is listed as a carcinogen by IARC. The IARC monograph examining the carcinogenic potential of ethanol examined only alcoholic beverages. No other components are listed as carcinogens by IARC, US OSHA or NTP.	

## Section 12: Ecological Information

**Environmental Overview:** See aquatic toxicity data, below:

**Toxicity:**

**Aquatic Toxicity: (Species, Method, End Point, Duration, Result)**

**Sirolimus**

Pseudokirchneriella subcapitata (Green Alga) OECD EC50 72 Hours 0.063 mg/L

**Persistence and Degradability:** No data available

**Bio-accumulative Potential:**

**Partition Coefficient: (Method, pH, Endpoint, Value)**

**Sirolimus**

Measured Log P >4.63

**Mobility in Soil:** No data available

## Section 13: Disposal Considerations

**Waste Treatment Methods**

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. 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

**The following refers to all modes of transportation unless specified below.**

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

## Section 15: Regulatory Information

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

**Sirolimus**

**CERCLA/SARA 313 Emission reporting** Not Listed

**California Proposition 65** Not Listed

**Standard for the Uniform Scheduling** Schedule 4

**for Drugs and Poisons:**

**EU EINECS/ELINCS List** Not Listed

**Section 16: Other Information**

**Issue Date: 14-11-2024**

**Version: 00**

**Further information**

**Revision date: NA**

**Revision note: NA.**

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.

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