

**SAFETY DATA SHEET**

Section 1: Identification	
<b>Material</b>	Teriflunomide Tablets 7 mg & 14 mg
<b>Manufacturer</b>	Annora Pharma Private Limited, Survey No. 261, Annaram Village, Gummadidala Mandal, Sangareddy, Telangana 502313, India (IND)
<b>Distributor</b>	Camber Pharmaceuticals, Inc., Piscataway, NJ 08854
Section 2: Hazard(s) Identification	
<b>Hazard Statements</b>	Harmful if swallowed
<b>Prevention</b>	Wash face, hands and any exposed skin thoroughly after handling.
<b>Ingestion</b>	IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell. Rinse mouth
<b>Disposal</b>	Dispose of contents/container to an approved waste disposal plant
Section 3: Composition/Information on Ingredients	
Name	CAS
Teriflunomide	163451-81-8
Corn Starch	9005-25-8
Sodium Starch Glycolate Type A	9063-38-1
Hydroxy Propyl cellulose	9004-64-2
Lactose Monohydrate	64044-51-5
Microcrystalline Cellulose	9004-34-6
Colloidal silicon dioxide	7631-86-9
Magnesium Stearate	557-04-0
Hypromellose	9004-65-3
Titanium Dioxide	13463-67-7
Polyethylene glycol	25322-68-3
Talc	14807-96-6
Yellow Iron oxide	1309-33-7

Section 4: First-Aid Measures	
<b>General Advice</b>	If symptoms persist, call a physician.
<b>Eye Contact</b>	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Get medical attention.
<b>Skin Contact</b>	Wash off immediately with plenty of water for at least 15 minutes. If skin irritation persists, call a physician.
<b>Inhalation</b>	Remove to fresh air. If not breathing, give artificial respiration. Get medical attention if symptoms occur.
<b>Ingestion</b>	Clean mouth with water and drink afterwards plenty of water. Get medical attention if symptoms occur
<b>Most important symptoms and effects</b>	None reasonably foreseeable
<b>Notes to Physician</b>	Treat symptomatically
Section 5: Fire-Fighting Measures	
<b>Suitable Extinguishing Media</b>	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Dry chemical, CO <sub>2</sub> , water spray or alcohol-resistant foam
<b>Unsuitable Extinguishing Media</b>	No information available
<b>Flash Point</b>	No information available
<b>Method -</b>	No information available
<b>Autoignition Temperature</b>	No information available
Section 6: Accidental Release Measures	
<b>Personal Precautions</b>	Ensure adequate ventilation. Use personal protective equipment as required. Avoid dust formation.
<b>Environmental Precautions</b>	Should not be released into the environment
<b>Methods for Containment and Clean-up</b>	Sweep up and shovel into suitable containers for disposal. Keep in suitable, closed containers for disposal
Section 7: Handling and Storage	
<b>Handling</b>	Wear personal protective equipment/face protection. Ensure adequate ventilation. Do not get in eyes, on skin, or on clothing. Avoid ingestion and inhalation. Avoid dust formation.

<b>Storage</b>	Keep container tightly closed in a dry and well-ventilated place. To maintain product quality. Store in freezer. Incompatible Materials. Oxidizing agent.
<b>8. Exposure controls / personal protection</b>	
<b>Exposure Guidelines</b>	This product does not contain any hazardous materials with occupational exposure limits established by the region-specific regulatory bodies.
<b>Engineering Measures</b>	Ensure adequate ventilation, especially in confined areas.
<b>Personal Protective Equipment</b>	
<b>Eye/face Protection</b>	Wear appropriate protective eyeglasses or chemical safety goggles as described by OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166.
<b>Skin and body protection</b>	Wear appropriate protective gloves and clothing to prevent skin exposure.
<b>Respiratory Protection</b>	Follow the OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirators if exposure limits are exceeded or if irritation or other symptoms are experienced.
<b>Section 9: Physical and Chemical Properties</b>	
<b>Physical state</b>	Tablet
<b>Description</b>	<p><b>Teriflunomide tablets, 7 mg</b> are light yellow to yellow colored, round shaped, biconvex, film-coated tablets debossed with 'H' on one side and 'T19' on the other side.</p> <p>Bottle of 30 tablets <span style="float: right;">NDC 31722-246-30</span></p> <p><b>Teriflunomide tablets, 14 mg</b> are white to off white colored, round shaped, biconvex, film-coated tablets debossed with 'H' on one side and 'T41' on the other side.</p> <p>Bottle of 30 tablets <span style="float: right;">NDC 31722-247-30</span></p> <p>Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature].</p>

## Section 10: Stability and Reactivity

<b>Reactive Hazard</b>	None known, based on information available
<b>Stability</b>	No information available.
<b>Conditions to Avoid</b>	Incompatible products
<b>Incompatible Materials</b>	Oxidizing agent
<b>Hazardous Decomposition Products</b>	Carbon monoxide (CO), Carbon dioxide (CO <sub>2</sub> ), Hydrogen fluoride, Nitrogen oxides (NO <sub>x</sub> )
<b>Hazardous Polymerization</b>	Hazardous polymerization does not occur.
<b>Hazardous Reactions</b>	None under normal processing.

## Section 11: Toxicological Information

### Acute Toxicity

#### Product Information

#### Component Information

**Toxicologically Synergistic** No information available

#### Products

### Delayed and immediate effects as well as chronic effects from short and long-term exposure

**Irritation** No information available

**Sensitization** No information available

**Carcinogenicity** The table below indicates whether each agency has listed any ingredient as a carcinogen.

Component	CAS No	IARC	NTP	ACGIH	OSHA	Mexico
Teriflunomide	163451-81-8	Not listed	Not listed	Not listed	Not listed	Not listed

**Mutagenic Effects** - No information available

**Reproductive Effects** - No information available.

**Developmental Effects** - No information available.

**Teratogenicity** - No information available.

**STOT - single exposure**- None known

**STOT - repeated exposure**- None known

**Aspiration hazard** -No information available

**Symptoms / effects,both acute and delayed**- No information available

**Endocrine Disruptor Information** -No information available

**Other Adverse Effects** -The toxicological properties have not been fully investigated

### Section 12: Ecological Information

**Ecotoxicity:** Do not empty into drains.

**Persistence and Degradability** No information available

**Bioaccumulation/ Accumulation** No information available.

**Mobility** No information available.

Component	log Pow
Teriflunomide	2,92

### Section 13: Disposal Considerations

#### Waste Disposal Methods

Chemical waste generators must determine whether a discarded chemical is classified as a hazardous waste. Chemical waste generators must also consult local, regional, and national hazardous waste regulations to ensure complete and accurate classification.

### Section 14: Transport Information

**DOT** Not regulated

**TDG** Not regulated

**IATA** Not regulated

### Section 15: Regulatory Information

#### United States of America Inventory

Component	CAS No	TSCA	TSCA Inventory notification - Active-Inactive	TSCA - EPA Regulatory Flags
Teriflunomide	163451-81-8	-	-	-

#### U.S. Federal Regulations

**SARA 313** -Not applicable

**SARA 311/312 Hazard Categories** See section 2 for more information

**CWA (Clean Water Act)**- Not applicable

**Clean Air Act**- Not applicable

**OSHA** - Occupational Safety and Health Administration- Not applicable

**CERCLA**- Not applicable

**California Proposition 65**- This product does not contain any Proposition 65 chemicals.

**U.S. State Right-to-Know Regulations** - Not applicable

**U.S. Department of Transportation**

Reportable Quantity (RQ): N

DOT Marine Pollutant N

DOT Severe Marine Pollutant N

**U.S. Department of Homeland**

**Security**

This product does not contain any DHS chemicals.

**Section 16: Other Information, including date of preparation or last revision**

**Issue Date: 13-03-2023**

**Version: 01**

**Further information**

**Revision date: 13-03-2023**

**Revision note: 01. Excipient details added in section 3.**

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.

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.