

SAFETY DATA SHEET

Section 1: Identification	
Material	Theophylline Anhydrous Extended-Release Tablets 300 mg and 450 mg
Recommended use	For treatment of asthma, bronchospasm, and COPD. Do not use without a prescription.
Manufacturer	Annora Pharma Private Limited, Survey No. 261, Annaram Village, Gummadidala Mandal, Sangareddy, Telangana 502313, India (IND)
Distributor	Camber Pharmaceuticals, Inc., Piscataway, NJ 08854
Section 2: Hazard(s) Identification	
Health Hazards	Not classified.
Physical Hazards	Not classified.
OSHA Regulatory Status	Drugs when in solid final form (e.g. capsules, tablets or pills) are considered exempt under the criteria of the Federal OSHA Hazard Communication Standard 29 CFR 1910.1200, Revision 3. However, in an industrial setting where a component's occupational
Label elements	Emergency Overview Normal precautions common to safe manufacturing practice should be followed in handling and storage.
Hazards not otherwise classified (HNOC)	Not applicable.
Other information	Not available.
Section 3: Composition/Information on Ingredients	
Active Ingredient	CAS
Theophylline Anhydrous	58-55-9
Lactose Monohydrate	10039-26-6
Hypromellose	9004-65-3
Povidone	25655-41-8
Magnesium stearate	557-04-0

Section 4: First-Aid Measures	
Eye Contact	In case of eye contact of broken tablets, immediately flush eyes with fresh water for at least 15 minutes while holding the eyelids open. Remove contact lenses if worn. Get medical attention if irritation persists.
Skin Contact	In case of contact broken tablets, remove contaminated clothing. Immediately wash exposed area with soap and water. Obtain medical attention if skin reaction occurs or irritation / symptoms persist.
Ingestion	In case of accidental ingestion, wash out mouth with copious amounts of water. Seek medical attention immediately. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.
Self-Protection of the First Aider	Do not use mouth-to-mouth method if victim ingested or inhaled the substance; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device.
Symptoms	Not available.
Note to Physicians	Treat symptomatically.
Section 5: Fire-Fighting Measures	
Suitable extinguishing media	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Unsuitable Extinguishing Media	No information available.
Specific hazards arising from the chemical	Toxic gas formation is possible during heating or fire.
Sensitivity to Mechanical Impact	None.
Sensitivity to Static Discharge	None.

Protective equipment and precautions for firefighters	Wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.
Section 6: Accidental Release Measures	
Personal Precautions	Evacuate personnel to safe areas. Use personal protection.
Methods for Containment	Prevent further leakage or spillage if safe to do so.
Methods for Cleaning Up	Pick up and transfer to properly labeled containers. Avoid creating dust.
Section 7: Handling and Storage	
Advice on Safe Handling	Do not break or crush tablets. If tablets are crushed and/or broken, avoid contact with skin, eyes or clothing. Wash thoroughly after handling. Wash contaminated clothing before reuse.
Storage Conditions	Dispense in a well-closed, container with child resistant closure. Store at 20°-25°C (68°-77°F).
Incompatible materials	Not available.
8. Exposure controls / personal protection	
Exposure Guidelines	This product, as supplied, contains the following hazardous material(s) with occupational exposure limits established by the region-specific regulatory bodies.
Chemical name	Magnesium stearate, NF 557-04-0
ACGIH TLV	TWA: 10 mg/m ³ inhalable particulate matter TWA: 3 mg/m ³ respirable particulate matter TWA: 10 mg/m ³ inhalable particulate matter except stearates of toxic metals TWA: 3 mg/m ³ respirable particulate matter except stearates of toxic metals
OSHA PEL	-
NIOSH IDLH	-

<p>Engineering Controls</p>	<p>None required for consumer use. In laboratories or industrial settings, handle material under adequate ventilation (e.g., chemical fume hood, vented balance enclosure [VBE]). Keep container tightly closed. Minimize the amount of material handled at any one time.</p>
<p>Eye/Face Protection</p>	<p>None required for consumer use. In laboratory, medical or industrial settings, safety glasses with side shields are recommended. The use of goggles or full-face protection may be required depending on the industrial exposure setting. Contact a health and safety professional for specific information.</p>
<p>Skin and Body Protection</p>	<p>None required for consumer use. In laboratory, medical or industrial settings, gloves and lab coats are recommended. The use of additional personal protective equipment such as shoe coverings, gauntlets, and hood or head coverings may be necessary. Contact a health and safety professional for specific information.</p>
<p>Respiratory Protection</p>	<p>None required for consumer use. Respirators may be required for certain laboratory and manufacturing tasks if engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (where the exposure limits have not been established). Workplace risk assessments should be completed before specifying and implementing respirator usage. All respirators must conform to specifications for efficiency and performance. In the United States of America, if respirators are used, a program should be instituted to assure compliance with OSHA Standard 29 CFR 1910.134. Contact a health and safety professional or manufacturer for specific information.</p>
<p>General Hygiene Considerations</p>	<p>Handle in accordance with good industrial hygiene and safety practice.</p>

Section 9: Physical and Chemical Properties	
Physical State	Solid
Description	<p>300 mg:</p> <p>White to off- white colored, capsule shaped, bevel edged, biconvex tablets, debossed with 'T' and score line on one side and 'V' on the other side.</p> <p>100's count 31722-077-01</p> <p>450 mg:</p> <p>White to off- white colored, capsule shaped, bevel edged, biconvex tablets, debossed with 'T' and '1' separated by a score line on one side and 'V' on the other side.</p> <p>100's count 31722-078-01</p>
Section 10: Stability and Reactivity	
Reactivity Stable at normal conditions.	Not available.
Chemical stability	Stable under recommended handling and storage conditions.
Possibility of hazardous	Not available.
Hazardous Polymerization	Not available.
Conditions to avoid	Not available.
Incompatible materials	Not available.
Hazardous decomposition	Not available.
Section 11: Toxicological Information	
Acute Toxicity	Theophylline Anhydrous: Oral LD50 - 225-250 mg/kg (Rat) Dermal LD50 - > 2000 mg/kg (Rabbit) Inhalation LC50 - > 6.7 mg/L (Rat) 4 h
Section 12: Ecological Information	
Ecotoxicity	0% of the mixture consists of component(s) of unknown hazards to the aquatic environment
Persistence and degradability	Not available.
Bioaccumulation	Not available.
Mobility	Theophylline is expected to have very high mobility in soil.
Section 13: Disposal Considerations	
Waste treatment methods	Disposal should be in accordance with applicable regional, national and local laws and regulations.
Section 14: Transport Information	
DOT	Not regulated
IATA	Not regulated

Section 15: Regulatory Information

International Inventories	
TSCA	Does not comply
DSL/NDSL	Does not comply
EINECS/ELINCS	Does not comply
ENCS	Does not comply
IECSC	Does not comply
KECL	Does not comply
PICCS	Does not comply
AICS	Does not comply

US Federal Regulations

SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

US State Regulations

California Proposition 65

This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations

This product does not contain any substances regulated by state right-to-know regulations.

U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable.

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

Issue Date: 15-11-2023

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.

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.