

Material Safety Data Sheet

SECTION 1 – CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

1. IDENTIFICATION	
Product Information	
Product Name	Acamprosate Calcium Delayed-Release Tablets, 333 mg
Jurisdiction	This Safety Data Sheet was prepared in accordance with the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) for the United States of America (USA) (CFR 1910.1200), European Union (EU) (EC 1272/2008) and United Nations (UN). The following countries utilize the UN GHS classification process: Mexico, Brazil, China, New Zealand, Canada, Japan, and Korea.
Active Substance	Acamprosate Calcium
Intended Uses	This Material is a finished drug product for patient use. Acamprosate Calcium Delayed-Release Tablets are indicated for the treatment of maintenance of abstinence from alcohol in patients with alcohol dependence who are abstinent at treatment initiation.
Company/Undertaking Identification	
Address	Somerset Therapeutics, LLC Somerset, NJ 08873
Emergency Phone No.	1-800-417-9175

2. HAZARDS IDENTIFICATION	
Statement of Hazard:	Non-hazardous in accordance with international standards for workplace safety.

3. COMPOSITION/INFORMATION ON INGREDIENTS		
Components	Quantity	CAS NO
Acamprosate Calcium	333 mg	-
Non-hazardous ingredients	Q.S	-

4. FIRST AID MEASURES	
Eye Contact:	Immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. Get medical attention.
Skin contact:	Wash skin thoroughly with soap and water. Get medical attention if irritation persists after washing. Remove contaminated clothing and shoes. Wash contaminated clothing before reuse. Destroy or thoroughly clean contaminated shoes.

Material Safety Data Sheet

Inhalation:	Move in to fresh air and keep at rest. For breathing difficulties, Oxygen may be necessary. Get medical attention. If breathing stops, provide artificial respiration.
Ingestion:	Do not induce vomiting unless directed to do so by medical personnel. Never give liquid to an unconscious person. Get medical attention.
Symptoms and Effects of Exposure:	For information on potential signs and symptoms of exposure, See Section 2 – Hazards Identification and/or Section 11 - Toxicological Information.

5. FIRE-FIGHTING MEASURES

Extinguishing Media:	Water spray, CO ₂ , dry chemical or alcohol resistant foam.
Unusual Fire & Explosion Hazards:	Emits toxic fumes under fire conditions.
Special Fire Fighting Procedures:	Self-Contained breathing apparatus and full protective clothing must be worn in case of fire.
Protective Measures:	Prevent runoff from fire control or dilution from entering streams, sewers, or drinking water supply.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions:	Use personal protective equipment. Immediately contact emergency personnel. Keep unnecessary personnel away. Follow all firefighting procedures.
Environmental precautions:	Do not release in to the environment.
Spill Cleanup methods:	Use a vacuum cleaner. If not possible, moisten dust with water before it is collected with shovel, broom or the like. Collect in containers and seal securely. For waste disposal, see section 13 of the SDS.

7. HANDLING AND STORAGE

General Handling:	Do not breathe dust. Avoid contact with eyes, skin, and clothing. Wash thoroughly after handling.
Storage Conditions:	Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Tablets are not considered hazardous under normal handling procedures and protective equipment is not required. The following are recommended for manufacturing or other situations where exposure to the powder may occur.	
Protective Measures: Minimize open handling. Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas.	

Material Safety Data Sheet

Respiratory Protection: Use a NIOSH approved respirator or an alternate approved dust mask should be used.
Hand Protection: Chemical resistant gloves
Eye Protection: Wear safety glasses with side shields (or goggles). If the work environment or activity involves dusty conditions, mist or aerosols, wear the appropriate goggles. Wear a face shield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
Skin and Body Protection: Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.
Hygiene Measures: Wash skin thoroughly with soap and water.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Solid, Tablets
Molecular Formula	-
Molecular Weight	-
Change in condition	
Melting point/Melting range	Undetermined
Boiling point/Boiling range	Undetermined
Flash point	Not applicable.
Flammability (solid, gaseous)	Product is not flammable.
Decomposition temperature	Not determined.
Auto igniting	Not determined
Danger of explosion	Product does not present an explosion hazard.

10. STABILITY AND REACTIVITY

Chemical Stability	Stable under normal conditions of use.
Conditions to Avoid:	Excessive heat & Moisture.
Incompatible Materials:	Strong oxidizers, Strong Bases and Strong Acids.
Hazardous Decomposition products:	Thermal decomposition or combustion may liberate irritating gases or vapors.

11. TOXICOLOGICAL INFORMATION

<u>General information:</u>	The information presented below pertains to the individual ingredients (Acamprosate Calcium), and not to the mixture(s) or final formulations.
<u>Inhalation:</u>	No data available.
<u>Ingestion:</u>	Harmful if swallowed.
<u>Skin Corrosion/irritation:</u>	No data available.
<u>Serious eye damage/eye irritation:</u>	No data available.

Material Safety Data Sheet

<u>Respiratory</u>	No data available.
<u>sensitizer/Skin sensitizer:</u>	
<u>Carcinogenesis</u>	No data available
<u>Mutagenesis</u>	No data available
<u>Impairment of Fertility</u>	No data available

12. ECOLOGICAL INFORMATION

General information: The information presented below pertains to the individual ingredients (Acamprostate Calcium), and not to the mixture(s) or final formulations.

Acute toxicity to Fish: No data available.

Acute toxicity to Aquatic Invertebrates: No data available.

Toxicity to Aquatic Plants: No data available.

Bioaccumulation: No data available.

Mobility: No data available.

13. DISPOSAL CONSIDERATIONS

Waste Disposal: Dispose of waste must be in accordance with all applicable Federal, State and local laws.

Measures for Avoidance and Recovery: Incineration is the most effective method of disposal in most instances. Do not allow runoff to sewer, waterway or ground. Operations that involve the crushing or shredding of waste materials or returned goods should take into account recommended exposure limits where they exist.

14. TRANSPORT INFORMATION

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

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

15. REGULATORY INFORMATION

United States of America

313 Toxic Release Inventory None
Inventory (40 CFR 372)

Section 302 Extremely Hazardous None
Substance (40 CFR 355,
Appendix A)

TSCA Inventory None

CERLA Hazardous Substance None
List (40 CFR 302.4)

16. OTHER INFORMATION

Prepared By Appco Pharma LLC

Material Safety Data Sheet

Additional Information About This Product	No data available.
Company Policy or Disclaimer	DISCLAIMER: This information is believed to be accurate and represents the best information currently available to us. However, we make no warranty of merchantability or any other warranty, express or implied, with respect to such information, and we assume no liability resulting from its use. Users should make their own investigations to determine the suitability of the information for their particular purposes.

END OF SDS SHEET