



SAFETY DATA SHEET

Lubiprostone Capsules, USP

1. IDENTIFICATION

Manufacturer:

Ascent Pharmaceuticals Inc
550 S.Research Place
Central Islip, NY 11722

Emergency Phone:

1-855-221-1622

Product Name: Lubiprostone Capsules, 8 mg an 24mg

Synonym(s): Not found.

Trade Name(s): Lubiprostone Capsules, 8 mg an 24mg

2.HAZARDS IDENTIFICATION

Not considered hazardous when handled under normal conditions. Accidental ingestion of large amounts may be harmful.

Classification of the Substance or Mixture

Patients/Consumers: Please refer to the product information insert or product label for appropriate consumer-specific information about this product when used according to the physician's directions

Classification: Not classified

Label elements: Not classified

Other Hazards: Exposure may aggravate pre-existing eye, skin, or respiratory conditions.

Unknown acute toxicity: No information available

3. COMPOSITION / INFORMATION ON INGREDIENTS

<u>Ingredient</u>	<u>CAS</u>	<u>Concentration %</u>
Lubiprostone	333963-40-9	0.004-0.012 % (approx.)
Excipients	NA	99.99 % (approx.)

4. FIRST AID MEASURES

Inhalation: No emergency procedures necessary for intact Capsules. In case of accidental inhalation, remove to fresh air. If breathing is difficult, give oxygen. If not breathing, give artificial respiration. Get medical attention if symptoms appear.

Eye Contact: No emergency procedures necessary for intact Capsules. If exposure occurs to crushed or broken capsules immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention if irritation occurs.

Skin Contact: No emergency procedures necessary for handling intact Capsules. If exposure occurs to crushed Capsules, wash with soap and water. Get medical attention if irritation develops. Take off contaminated clothing and wash before reuse.

Ingestion: If swallowed, rinse mouth with water (only if the person is conscious). If ingestion of a large amount does occur, call a poison control center immediately

Indication of immediate medical attention and special treatment needed:

No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information Centre.

General information Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Pre-placement and periodic health surveillance is not usually indicated. The final determination of the need for health surveillance should be determined by local risk assessment.



5. FIRE-FIGHTING MEASURES

Extinguisher Media: Use foam or all-purpose dry chemicals to extinguish. This material is harmful to aquatic organisms. Fire water contaminated with this material must be contained and prevented from being discharged to any water way, sewer or drain.

Firefighting Procedures: As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

Fire and Explosion Hazards: None known under normal conditions of product handling.

Hazardous Decomposition Products: gases hazardous to health may be formed.

6. ACCIDENTAL RELEASE MEASURES

The following are recommended for manufacturing or other situations where exposure may occur.

Personal Precautions: Not necessary for small spills. For large spills, immediately contact emergency personnel. Keep unnecessary personnel away. Use suitable protective equipment.

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.

7. HANDLING AND STORAGE

Handling: Restrict access to working area. No special control measures required for the normal handling of this product. Keep away from heat, sparks and open flame. Store in original tightly closed container. Store away from incompatible materials. If Capsules are crushed and/or broken, avoid breathing avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment. Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases.

Storage Conditions: Controlled Room Temperature: 20° to 25° C (68° to 77° F).



Store the medicine in a tight, light resistant container at room temperature, away from heat, moisture, and direct light.

8.EXPOSURE CONTROLS / PERSONAL PROTECTION

Capsules are not considered hazardous under normal handling procedures and the following are recommended for manufacturing or other situations where exposure may occur.

Engineering Controls: Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls.

Personal Protective Equipment:

Eye/Face Protection: Wear safety glasses with side shields wherever the potential exists for direct exposure to capsules.

Skin Protection: Use disposable chemical resistant gloves

Respiratory Protection: None required with normal handling of finished product. Use a NIOSH approved respirator or an alternate approved dust mask should be used.

Additional Exposure Precautions: None required with normal handling of finished product. Use disposable outer garments or chemical resistant garments of equal or greater protection, when there is potential for direct contact with crushed or leaking capsules. Protect exposed skin.

9.PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Solid (Capsule)

Boiling Point: Not available

Melting range: Not available

Specific Gravity: Not available

Evaporation Rate: Not available

Water Solubility: Not available

Vapor Density: Not available.

Vapor Pressure: Not available.

Revision:00

Effective Date:21-May-2025



10. STABILITY AND REACTIVITY

Stability: The product is stable under recommended storage conditions.

Conditions to avoid: Keep away from heat, sparks and open flame. Contact with incompatible materials.

Incompatibilities: Strong oxidizing agents

Hazardous Decomposition Products: No data available

11. TOXICOLOGICAL INFORMATION

General: Handling of formulated product is not expected to cause any adverse effects. The data pertains to the ingredient in formulations, rather than this specie formulation.

12. ECOLOGICAL INFORMATION

Eco-toxicity: No information is available about the potential of this product to produce adverse environmental effects.

Avoid release in to the environment

Runoff from fire control or dilution water may cause pollution.



13.DISPOSAL CONSIDERATIONS

Waste Disposal: Dispose of waste in accordance with all applicable Federal, State, or local regulations.

14.TRANSPORT INFORMATION

Regulatory Organizations:

DOT: Not Regulated

IATA: Not Regulated

IMDG: Not Regulated

15.REGULATORY INFORMATION

Below is selected regulatory information chosen primarily for possible Ascent and Company usage. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

Safety, health and environmental regulations: This safety data sheet was prepared according to GHS. Being pharmaceutical product, this product is not subject to GHS-related regulations (labelling, SDS, and others).

16.OTHER INFORMATION

SDS Sections Revised: New SDS

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS MATERIAL SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute or product literature which may accompany the finished product.

GLOSSARY:

CAS Number = Chemical Abstract Service Registry Number

CERCLA = Comprehensive Environmental Response Compensation and Liability Act (of 1980)

DOT = Department of Transportation

ECG = Electrocardiography

IARC = International Agency for Research on Cancer

ICAO/IATA = International Civil Aviation Organization/ International Air Transport Association

IMO = International Maritime Organization

MSDS = Material Safety Data Sheet

NA = Not Applicable

NIOSH = National Institute for Occupational Safety and Health

NTP = National Toxicology Program

OSHA = Occupational Safety and Health Administration

SARA = Superfund Amendments and Reauthorization Act

SSRI's = Selective serotonin reuptake inhibitor

TSCA = Toxic Substances Control Act