

SAFETY DATA SHEET

Sevelamer Carbonate Tablets

1. IDENTIFICATION

Manufacturer:

InvaGen Pharmaceuticals Inc
7, Oser Avenue
Hauppauge, NY 11788

Emergency Phone:

1-631-231-3233

Common Name: Sevelamer Carbonate Tablets

Chemical Family: Cross-linked poly (allylamine carbonate) polymer

Synonym(s): Not Applicable

Chemical Name: Poly (allylamine-co-N, N-diallyl-1, 3-diamino-2-hydroxypropane) carbonate.

Trade Name(s): Sevelamer Carbonate Tablets 800 mg.

Therapeutic Category: Treatment of hyperphosphatemia includes reduction in dietary intake of phosphate, inhibition of intestinal phosphate absorption with phosphate binders, and removal of phosphate with dialysis.

Molecular formula and weight: $(C_3H_7N.nH_2CO_3)_{812z}$ $(C_9H_{18}N_2nH_2CO_3)_{94z}$ where z = a large number **and Wt.:** Variable

2. HAZARDS IDENTIFICATION

Not considered hazardous when handled under normal conditions.

EMERGENCY OVERVIEW

Caution Statement: Intact Sevelamer Carbonate Tablets are not considered to be a health hazard.

Routes of Entry: Oral

Effects of Overexposure: Tablets are intended for human consumption under guidance of a physician. Intact tablets are not considered hazardous under normal handling procedures.

Medical conditions Aggravated by Long Term Exposure: No Data Available.

Carcinogenicity: Sevelamer Carbonate - Not listed by IARC, NTP and OSHA.

3.COMPOSITION / INFORMATION ON INGREDIENTS

<u>Ingredient</u>	<u>CAS</u>	<u>Concentration</u>
		<u>800 mg</u>
Sevelamer Carbonate	845273-93-0	≈ 60.1%
Excipients	NA	≈ 39.9%

Contains no hazardous components (one percent or greater) or carcinogens (one-tenth percent or greater) not listed above.

* All Concentrations are percent by weight.

4. FIRST AID MEASURES

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.

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.

Eye Contact: Immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. Get medical attention.

Ingestion: Do not induce vomiting unless directed to do so by medical personnel. Never give liquid to an unconscious person. Get medical attention.

Notes to the Physician:

Sevelamer carbonate, a non-absorbed phosphate binding cross-linked polymer, free of metal and calcium. It contains multiple amines separated by one carbon from the polymer backbone. These amines exist in a protonated form in the intestine and interact with phosphate molecules through ionic and hydrogen bonding. By binding phosphate in the gastrointestinal tract and decreasing absorption, Sevelamer carbonate lowers the phosphate concentration in the serum (serum phosphorus).

Overdose Treatment:

There are no reports of over dosage with Sevelamer carbonate in patients. Since Sevelamer is not absorbed, the risk of systemic toxicity is low.

5.FIRE-FIGHTING MEASURES

Extinguishing Media: Water spray, CO₂, 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

Handling: Do not breathe dust. Avoid contact with eyes, skin, and clothing. Wash thoroughly after handling.

Storage: Keep container tightly closed in a cool, well-ventilated place. Keep away from heat and direct sun light.

8.EXPOSURE CONTROLS / PERSONAL PROTECTION

Compressed 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.

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 Properties:

Physical State: Solid

Form: Tablets

Appearance:

Sevelamer Carbonate Tablets, 800 mg – Off-white, film coated, modified capsule shaped, biconvex tablets debossed with “I 8” on one side.

10. STABILITY AND REACTIVITY

Possibility of hazardous reactions: Stable under ordinary conditions of use and storage.

Conditions to avoid: Excessive heat & Moisture.

Incompatible materials: Strong oxidizers.

Hazardous Decomposition products: Thermal decomposition or combustion may liberate irritating gases or vapors.

11. TOXICOLOGICAL INFORMATION

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

Inhalation: No data available.

Ingestion: May be harmful if swallowed.

Skin Corrosion/ irritation: No data available.

Serious eye damage/eye irritation: No data available.

Respiratory sensitizer/Skin sensitizer: No data available.

Carcinogenicity: Standard lifetime carcinogenicity bioassays were conducted in mice and rats. Rats were given Sevelamer hydrochloride by diet at 0.3, 1, or 3 g/kg/day. There was an increased incidence of urinary bladder transitional cell papilloma in male rats of the high dose group (human equivalent dose twice the maximum clinical trial dose of 13 g). Mice received dietary administration of Sevelamer hydrochloride at doses of up to 9 g/kg/day (human equivalent dose 3 times the maximum clinical trial dose). There was no increased incidence of tumors observed in mice.

Mutagenesis: In an in vitro mammalian cytogenetic test with metabolic activation, Sevelamer hydrochloride caused a statistically significant increase in the number of structural chromosome aberrations. Sevelamer hydrochloride was not mutagenic in the Ames bacterial mutation assay.

Reproductive Toxicity: Sevelamer hydrochloride did not impair the fertility of male or female rats in a dietary administration study in which the females were treated from 14 days prior to mating through gestation and the males were treated for 28 days prior to mating. The highest dose in this study was 4.5 g/kg/day (human equivalent dose 3 times the maximum clinical trial dose of 13 g).

Other information:

The most common adverse reactions are pruritus, rash, abdominal pain, fecal impaction, and uncommon cases of ileus, intestinal obstruction, and intestinal perforation.

Appropriate medical management should be given to patients who develop constipation or have worsening of existing constipation to avoid severe complications.

12.ECOLOGICAL INFORMATION

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

Ecotoxicity: No data available.

Acute toxicity (Aquatic invertebrates): 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

DOT: Not Regulated

IMDG: Not regulated

ICAO/IATA: Not Regulated

IMO: Not Regulated

15.REGULATORY INFORMATION

Stated regulatory information chosen primarily for possible usage of InvaGen Pharmaceutical, Inc. 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.

U.S. Regulatory Information

CERLA Hazardous Substance List (40 CFR 302.4): None

TSCA : None

SARA Title III

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

Section 313 Toxic Release Inventory (40 CFR 372): None

16.OTHER INFORMATION

SDS Sections Revised: New

GLOSSARY:

SDS	Safety Data Sheet
NA	Not Applicable
CAS Number	Chemical Abstract Service Registry Number
NTP	National Toxicology Program
NIOSH	National Institute for Occupational Safety and Health
DOT	Department of Transportation
IMDG	International Maritime Dangerous Goods Code
ICAO	International Civil Aviation Organization
IATA	International Air Transport Association
IMO	International Maritime Organization
TSCA	Toxic Substances Control Act
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
SARA	Superfund Amendments and Reauthorization Act
OSHA	Occupational Safety and Health Administration

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