

## Safety Data Sheet

### Sevelamer Carbonate Tablets, USP, 800mg

#### SECTION 1 IDENTIFICATION

**Product identifier** Sevelamer Carbonate Tablets, USP, 800mg  
**Recommended use** Oral  
**Manufacturer**  
**Company name** TWi Pharmaceuticals, Inc.  
**Address** 3F, No 41, Lane 221, Kang Chien Rd, Taipei, Taiwan.  
**Telephone** 886-2-26573350  
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**E-mail address** QA.Service@twipharma.com  
**Emergency phone number** 1-844-518-2989

#### SECTION 2 HAZARD IDENTIFICATION

Classification of the finished drug product is not required according to OSHA 29 CFR 1910.1200. The following information is provided for the drug substance, sevelamer carbonate

**Hazard statement** Suspected of damaging fertility of unborn child.  
 May be harmful if swallowed  
 Harmful to aquatic life.  
 Harmful to aquatic life with long lasting effects

**Precautionary statement** Do not get in eyes, on skins, or on clothing.  
 Wash thoroughly after handling  
 Use personal protective equipment as required  
 Call poison center or doctor/physician if you fell unwell

#### SECTION 3 COMPOSITION/INFORMATION ON INGREDIENTS

Ingredient	Exposure Limit	CAS#
Sevelamer carbonate	Not founded	845273-93-0
Non-hazardous excipients	Not founded	-

#### SECTION 4 FIRST-AID MEASURES

**Inhalation** If dust from broken tablets is inhaled, remove to fresh air. If breathing is difficult, trained personnel should give oxygen. Get medical attention.

**Skin contact** In case of contact with broken tablets, immediately flush skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if irritation develops and persists.

**Eye contact** In case of contact with dust from broken tablets, immediately flush eyes with plenty of water for at least 15 minutes. If easy to do, remove contact lenses if worn. Get medical attention.

**Ingestion** If swallowed, call a poison center or physician immediately. Do NOT induce vomiting unless directed to do so by a physician. Never give anything by

mouth to an unconscious person. Rinse mouth thoroughly with water.

## SECTION 5 FIRE-FIGHTING MEASURES

### Extinguishing Media

All means: water, carbon dioxide, foam or dry chemical.

### Special Protective Equipment and Precautions for Fire-fighters

In case of fire, use full firefighting turnout (bunker) gear and self-contained breathing apparatus (SCBA). Keep personnel upwind and away from fire. Move container from fire area if you can do it without risk. Do not scatter spilled material with high-pressure water streams. Dike fire-control water for later disposal.

## SECTION 6 ACCIDENTAL RELEASE MEASURES

### Personal precautions and Protective Equipment

Eye protection, respiratory protective equipment, and suitable protective clothing should be worn if significant dust emissions are generated from broken or crushed tablets

### Emergency Procedures

Follow local workplace procedures. Prevent the product from entering the environment. Avoid discharges to sewers, drains, waterways, or onto the ground.

### Methods for Containment

Vacuum or scoop up, moisten any dust with water before collection with a shovel or broom

### Methods for Clean-up

Place material in suitable container for disposal. Wash the floor with plenty of water, absorb or retain the cleaning water for disposal.

## SECTION 7 HANDLING AND STORAGE

### Handling

Use with adequate ventilation. Avoid breathing dust if tablets are crushed or spilled. Do not get dust in eyes or on skin. Wash thoroughly after handling.

### Storage

Keep container tightly closed. Store at 20°C to 25°C (68°F to 77°F).

## SECTION 8 EXPOSURE CONTROLS/PERSONAL PROTECTION

**Appropriate Engineering Controls** Provide adequate ventilation. No other specific controls are needed under normal handling conditions.

### Individual Protection Measures

#### Eye/face protection

Safety glasses or safety goggles should be worn if there is a potential for dust exposure from broken or crushed tablets.

#### Skin protection

Suitable protective gloves should be worn if handling the unfinished product or broken or crushed tablets.

#### Respiratory protection

None normally required. Approved respiratory protection should be worn if there is a potential for exposure to dust from handling operations or from broken or crushed tablets.

#### General hygiene considerations

Suitable work clothes. Wash hands before breaks and at the end of the work shift.

## SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

### Appearance

<b>Physical state/ Form</b>	White oval film-coated tablets
<b>Odor</b>	No data available
<b>Odor threshold</b>	No data available
<b>pH (sevelamer carbonate)</b>	8 - 10.5 (1% aqueous slurry)
<b>Melting point/ Freezing point</b>	Not applicable
<b>Initial boiling point/boiling point range</b>	Not applicable
<b>Flash point</b>	Not applicable
<b>Evaporation rate</b>	Not applicable
<b>Flammability</b>	Not applicable
<b>Upper/lower flammability or explosive limits</b>	Not applicable
<b>Vapor pressure/Vapor density</b>	Not applicable
<b>Relative density</b>	0.4 - 0.8 mg/ml (Sevelamer carbonate bulk).
<b>Solubility</b>	Insoluble in aqueous and organic solvents; hydrophilic; swells in water.
<b>Partition coefficient</b>	n-octanol/water: Not applicable. Insoluble in aqueous and organic solvents.
<b>Auto-ignition temperature</b>	No data available.
<b>Decomposition temperature</b>	No data available.
<b>Viscosity</b>	Not applicable

## SECTION 10 STABILITY AND REACTIVITY

Stable under normal conditions of use.

## SECTION 11 TOXICOLOGICAL INFORMATION

<b>Exposure Route</b>	No data available
<b>Symptoms/Health Effect</b>	No data available
<b>Acute toxicity (LD50)</b>	LD50, mouse, oral: >3.2 g/kg. Preclinical and clinical studies with sevelamer carbonate indicate that it is not systemically absorbed following ingestion.
<b>Chronic toxicity and long-term toxicity</b>	FDA assigned-pregnancy categories: Category_ C Animal reproduction study have showed an adverse effect on the fetus and there is no adequate and well-controlled studies in humans, but potential benefits may warrant use of the drug pregnant women despite potential risk

## SECTION 12 ECOLOGICAL INFORMATION

Harmful to aquatic life with long lasting effects

## SECTION 13 DISPOSAL CONSIDERATIONS

Disposal should be in accordance with applicable regional, national and local laws and regulations. Local regulations may be more stringent than regional or national requirements

## SECTION 14 TRANSPORT INFORMATION

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

## SECTION 15 REGULATORY INFORMATION

Generic Medicine

## SECTION 16 OTHER INFORMATION

No information found.

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