

## SAFETY DATA SHEET

**Balsalazide Disodium Capsules USP, 750 mg**

**Version: 01**

**Issue Date: 04/09/2025**

**1. IDENTIFICATION:**

**Product Name:** Balsalazide Disodium Capsules USP

**Recommended Use:** Rx. Pharmaceutical. Treatment of mild to moderate active ulcerative colitis

**Recommended Restrictions:** None known.

**Manufacturer/Distributor Information:** **Carnegie Pharmaceuticals LLC**  
600 Delran Parkway,  
Delran, New Jersey, 08075  
USA  
Emergency: (732) 783-7011 or call 911  
Information: (732) 783-7011

**2. HAZARDS IDENTIFICATION:**

**Hazard Classification:**

**Physical Hazards:** Not Classified

**Health Hazards:** Not Classified

**OSHA defined Hazards:** Not Classified

**Label elements**

**Hazard Symbol:** None.

**Signal Word:** Warning

**Hazard Statement:** This is a pharmaceutical product designed to be prescribed by a licensed health care professional. Should any person while using this product observe any adverse health effects, they should seek medical treatment.

**Precautionary Statement**

**Prevention:** Observe good industrial hygiene practices.

**Response:** Wash hands after handling

**Storage:** Store away from incompatible materials. Store between 20° to 25°C (68° to 77°F); excursions permitted between 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].

**Disposal:** Incineration of waste at an approved USEPA incinerator is recommended.

**Hazard(s) not otherwise classified (HNOC):** None known.

**3. COMPOSITION / INFORMATION ON INGREDIENT:**

<b>Ingredient</b>	<b>CAS number</b>
Balsalazide Disodium Dihydrate, USP	150399-21-6
Silicon Dioxide, NF	7631-86-9
Magnesium Stearate, NF	557-04-0

**4. FIRST AID MEASURES:**

**Description of Most important symptoms and effects, both acute and delayed, and first-aid measures.**

**Inhalation:** If powder from the material is inhaled, remove the affected person immediately to fresh air Call a physician if symptoms develop or persist.

**Skin Contact:** Wash off with soap and water. Get medical attention if irritation develops and persists.

**Eye Contact:** Rinse with water. Get medical attention if irritation develops and persists.

## SAFETY DATA SHEET

**Balsalazide Disodium Capsules USP, 750 mg**

**Version: 01**

**Issue Date: 04/09/2025**

**Ingestion:** Rinse mouth. Get medical attention if symptoms occur. If ingestion of a large amount does occur, call a poison control center immediately.

**Most important symptoms/effects, acute and delayed:** The common side effects include headache, abdominal pain, diarrhea, nausea, vomiting, respiratory infection, and arthralgia.

**Indication of immediate medical attention and special treatment needed:** If an overdose occurs, treatment should be supportive with particular attention to correction of electrolyte abnormalities. Treat symptomatically.

**General Information:** Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves.

**First-Aid Measures after Eye Contact:** Flush eye(s) immediately with plenty of water. Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes.

**Symptoms/Injuries After Ingestion:** May cause adverse effects as described in product insert when ingested.

**First-aid Measures After Ingestion:** Acute overdosage should be followed by immediate gastric lavage or emesis followed by supportive and symptomatic therapy. Contact a physician.

**Chronic Symptoms:** None expected under normal conditions of use.

### 5. FIRE FIGHTING MEASURES:

**Extinguishing Media:** Water fog, Foam, Dry chemical powder, carbon dioxide

**Unsuitable Extinguishing Media:** Do not use water jet as an extinguisher, as this will spread fire

**Special Hazards Arising from the substance or Mixture.**

During fire, gaseous hazards to health may be observed.

**Special protective equipment and precautions for firefighters:** Self-contained breathing apparatus and full protective clothing must be worn in case of fire

**Firefighting Instructions:** Use water spray to cool unopened containers

**Specific Methods:** Use standard firefighting procedures and consider the hazards of other materials involved.

**General fire hazards:** No unusual fire or explosion hazards noted.

### 6. ACCIDENTAL RELEASE MEASURES:

**Personal Precautions, Protective Equipment and Emergency Procedures.**

**General Measures:** Keep unnecessary personnel away. Wear appropriate personal protective equipment.

**Methods and materials for containment and cleaning up:** Sweep up and place into a proper container for disposal. Minimize dust generation and accumulation. Collect dust using a vacuum cleaner equipped with HEPA filter. Following product recovery, flush the area with water. Incineration of waste at an approved USEPA incinerator is recommended.

**Environmental Precautions:** Avoid discharge into drains, water courses or onto the ground.

### 7. HANDLING AND STORAGE:

**Precautions for Safe handling:** Avoid contact with eyes, skin, and clothing. Avoid breathing dust. Wash hands thoroughly after handling.

**Conditions for safe storage, including any incompatibilities:** Store between 20° to 25°C (68° to 77°F); excursions permitted between 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].

## SAFETY DATA SHEET

**Balsalazide Disodium Capsules USP, 750 mg**

**Version: 01**

**Issue Date: 04/09/2025**

### **8. EXPOSURE CONTROLS / PERSONAL PROTECTION:**

**Occupational exposure limits:** No exposure limits noted for ingredient(s).

**Biological limit values:** No biological exposure limits noted for the ingredient(s).

**Appropriate engineering controls:** Ventilation should be matched to conditions.

**Individual protection measures, such as personal protective equipment**

**Eye/face protection:** None for consumer use

**Skin and Body Protection:** None for consumer use

**Respiratory Protection:** None required for consumer use

**Thermal Hazards:** Wear appropriate thermal protective clothing, when necessary

**General Hygiene Considerations:** Always observe good personal hygiene measures, such as washing hands after handling the material and before eating, drinking and/or smoking.

### **9. PHYSICAL AND CHEMICAL PROPERTIES:**

**Appearance:** Light Orange Opaque Capsules

**Strength:** 750 mg

**Physical State:** Solid

**Color:** Light Orange

**Odor:** None

**Molecular Formula:** C<sub>17</sub>H<sub>13</sub>N<sub>3</sub>O<sub>6</sub>Na<sub>2</sub> · 2H<sub>2</sub>O

**Molecular Weight:** 437.32

### **10. STABILITY AND REACTIVITY:**

**Reactivity:** The product is stable and non-reactive under normal conditions of use, storage and transport

**Chemical Stability:** This is a stable material under normal conditions.

**Possibility of Hazardous Reactions:** No dangerous reaction known under conditions of normal use

**Conditions to Avoid:** Contact with incompatible materials. Avoid dispersal of dust in the air

**Incompatible Materials:** Strong oxidizing agents

**Hazardous Decomposition Products:** No hazardous decomposition products are known.

### **11. TOXICOLOGICAL INFORMATION:**

**Information on likely routes of exposure**

**Inhalation:** Not expected to be hazardous in final pharmaceutical form. Mechanical processing may generate dust. Inhalation of powder may cause respiratory irritation

**Skin contact:** Not expected to be hazardous in final pharmaceutical form. Powder may irritate the skin

**Eye contact:** Not expected to be hazardous in final pharmaceutical form. Powder may cause mechanical irritation

**Ingestion:** Ingestion may cause irritation and malaise.

**Symptoms related to the physical, chemical and toxicological characteristics:** The common side effects are headache, abdominal pain, diarrhea, nausea, vomiting, respiratory infection, and arthralgia

**Information on toxicological effects**

**Acute toxicity:** Not expected to be acutely toxic.

**Skin corrosion/irritation:** Prolonged skin contact may cause temporary irritation.

**Serious eye damage/eye irritation:** Powder in the eyes may cause irritation

**Respiratory or skin sensitization**

**Respiratory sensitization:** Not a respiratory sensitizer.

## SAFETY DATA SHEET

**Balsalazide Disodium Capsules USP, 750 mg**

**Version: 01**

**Issue Date: 04/09/2025**

**Skin sensitization:** May cause an allergic skin reaction.

**Germ cell mutagenicity:** Laboratory experiments have shown mutagenic effects.

**Carcinogenicity:** This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

**OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)**

Not listed.

**Reproductive toxicity:** Pregnancy Category B. It is not known whether this product is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when administering to a nursing woman

**Specific target organ toxicity - single exposure:** Not classified.

**Specific target organ toxicity - repeated exposure:** Not classified.

**Aspiration hazard:** Due to the physical form of the product it is not an aspiration hazard.

**Further information:** See package insert.

### **12 ECOLOGICAL INFORMATION:**

**Ecotoxicity:** The product is not classified as environmentally hazardous.

**Persistence and degradability:** No data is available on the degradability of this product.

**Bio-accumulative potential:** No data available.

**Mobility in soil:** No data available.

**Other adverse effects:** None.

### **13 DISPOSAL CONSIDERATIONS:**

**Disposal instructions:** Collect and reclaim or dispose in sealed containers at licensed waste disposal site.

**Local disposal regulations:** Dispose in accordance with all applicable regulations.

**Hazardous waste code:** The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

**Waste from residues / unused products:** Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

**Contaminated packaging:** Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

### **14 TRANSPORT INFORMATION:**

Not regulated as dangerous goods for transport.

### **15 REGULATORY INFORMATION:**

**Prescription Drug status:** Rx only

**US Federal Regulations:** This material is not listed on the US TSCA Inventory. Therefore, it can only be used for TSCA exempt purposes such as R&D or drug use.

### **16 OTHER INFORMATION: \_\_\_**

No other information is available.

**SAFETY DATA SHEET**

**Balsalazide Disodium Capsules USP, 750 mg**

**Version: 01**

**Issue Date: 04/09/2025**

\*\*\*\*\*  
\*\*\*\*\* The information herein is provided in good faith and is believed to be accurate as of the effective date shown. However, no warranty, express or implied, is given. Carnegie Pharmaceutical LLC makes no representation as to the comprehensiveness or accuracy of the information. Conditions of use are beyond Carnegie Pharmaceutical LLC's control and therefore, users are responsible to verify this data under their own operating conditions to determine whether the product is suitable for their particular purposes, and they assume all risks of their use, handling, and disposal of the product. Carnegie Pharmaceutical LLC expressly disclaims any and all liability as to any results obtained, or arising from, any use of this publication or reliance upon information contained herein.  
\*\*\*\*\*