



# SAFETY DATA SHEET

## Ibuprofen and Famotidine Tablets 800 mg / 26.6 mg

### 1. IDENTIFICATION

**Manufacturer:**

Ascent Pharmaceuticals Inc  
400 S. Technology Drive  
Central Islip, NY 11722  
USP

**Emergency Phone:**

1-855-221-1622

**Common Name:** Ibuprofen and Famotidine Tablets 800 mg / 26.6 mg

**Trade Name(s):** Ibuprofen and Famotidine Tablets 800 mg / 26.6 mg.

### 2. HAZARDS IDENTIFICATION

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

### EMERGENCY OVERVIEW

**Caution Statement:** Intact Ibuprofen and Famotidine Tablets are not considered to be a health hazard. Accidental ingestion of large amounts may be harmful.

**Routes of Entry:** Ingestion

### 3.COMPOSITION / INFORMATION ON INGREDIENTS

<u>Ingredient</u>	<u>CAS</u>	<u>Concentration</u>
Ibuprofen	15687-27-1	≈ 67%
Famotidine	76824-35-6	≈ 8%
Excipients	NA	≈ 25%

### 4. FIRST AID MEASURES

**Inhalation:** Should not pose a hazard in the final form. If breathing is difficult, move to fresh air. Get medical attention immediately.

**Skin Contact:** Wash with soap and water. Get medical attention if symptoms occur.

**Eye Contact:** Any material that contacts the eye should be washed out immediately with water. If easy to do, remove contact lenses if worn. Get medical attention if symptoms persist.

**Ingestion:** Call a physician or poison control center immediately.

**Most important symptoms and effects, both acute and delayed:** See product insert.

**Indication of immediate medical attention and special treatment needed.**

**Notes to Physician:** Treat symptomatically.

### 5.FIRE-FIGHTING MEASURES

**Extinguishing Media:** Use water spray, dry chemical, carbon dioxide or material appropriate for fire in surrounding area

**Unusual Fire & Explosion Hazards:** Not Applicable.



**Special Fire Fighting Procedures:** Wear full protective clothing and self-contained breathing apparatus.

**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:** Not required when handling tablets or containers. Ventilation should be matched to conditions.

**Respiratory Protection:** Not required when handling tablets or containers. NIOSH/MSHA approved respirators for protection should be used if respirators are found to be necessary. Ventilation should be matched to conditions.

**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:** Not required when handling tablets. If containers are compromised or exposure is likely --wear: Goggles, Lab Coat and Gloves

**Hygiene Measures:** Wash skin thoroughly with soap and water.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

**Physical Properties:**

**Physical State:** Solid

**Form:** Tablets

## 10. STABILITY AND REACTIVITY

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

**Conditions to avoid:** Excessive heat & Moisture.

**Incompatible materials:** None known.

**Hazardous Decomposition products:** Will not occur.

## 11. TOXICOLOGICAL INFORMATION

**Acute toxicity:** Oral: Harmful if swallowed.

<b>Ibuprofen and Famotidine Tablets 800 mg / 26.6 mg</b>	
ATE US (oral)	766.265 mg/kg bodyweight
<b>Ibuprofen (15687-27-1)</b>	
LD50 oral rat	636 mg/kg ; 740 mg/kg mice; 1400 mg/kg rabbits
ATE US (oral)	636.000 mg/kg bodyweight
<b>Famotidine (76824-35-6)</b>	
LD50 oral rat	> 3000 mg/kg



**Skin corrosion/irritation:** No hazard expected under normal handling conditions.

**Serious eye damage/irritation:** No hazard expected under normal handling conditions.

**Respiratory or skin sensitization:** No hazard expected under normal handling conditions.

**Germ cell mutagenicity:** No hazard expected under normal handling conditions.

**Carcinogenicity:** No hazard expected under normal handling conditions.

**Reproductive toxicity:** No hazard expected under normal handling conditions.

**STOT - single exposure:** No hazard expected under normal handling conditions.

**STOT - repeated exposures:** No hazard expected under normal handling conditions.

**Aspiration hazard:** No hazard expected under normal handling conditions

## 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

**ICAO/IATA:** Not Regulated



## **15.REGULATORY INFORMATION**

Stated regulatory information chosen primarily for possible usage of Ascent 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**

Not Applicable

## **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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