

# Scientific Documentation

## Famotidine, USP

Not appropriate for regulatory submission.

Please visit [www.spectrumchemical.com](http://www.spectrumchemical.com) or contact Tech Services for the most up-to-date information contained in this information package.

Spectrum Chemical Mfg Corp  
769 Jersey Avenue  
New Brunswick, NJ 08901  
Phone 732.214.1300



## **Table of Contents**

Product Specification  
Certificate of Analysis  
Safety Data Sheet (SDS)  
Certification of Current Good Manufacturing Practices (cGMP)  
Manufacturing Process Flowchart  
Technical Statements  
Elemental Impurities Statement  
Residual Solvents Statement  
General Label Information – Sample Label

## Specification for Famotidine, USP (F1154)

Item Number	F1154
Item	Famotidine, USP
CAS Number	76824-35-6
Molecular Formula	C <sub>8</sub> H <sub>15</sub> N <sub>7</sub> O <sub>2</sub> S <sub>3</sub>
Molecular Weight	337.45
MDL Number	
Synonyms	3-[(2-Diaminomethyleneaminothiazol-4-yl)methylthio]-N-sulfamoylpropionamidine

Test	Specification	
	Min	Max
ASSAY (DRIED BASIS)	98.5	101.0 %
LOSS ON DRYING		0.5 %
RESIDUE ON IGNITION		0.1 %
ELEMENTAL IMPURITIES	AS REPORTED	
ORGANIC IMPURITIES:		
Famotidine related compound D		0.3 %
Famotidine related compound C		0.3 %
Famotidine cyanoamidine		0.2 %
Famotidine related compound F		0.1 %
Famotidine amidine		0.2 %
Famotidine related compound B		0.3 %
Famotidine related compound E		0.3 %
Any other individual impurity		0.1 %
Total impurities		1.0 %
IDENTIFICATION (FTIR)	SPECTRUM MATCHES REFERENCE	
APPEARANCE		
EXPIRATION DATE		
DATE OF MANUFACTURE		
RESIDUAL SOLVENTS	AS REPORTED	
CLASS 2 (SOLVENT) / METHANOL	.	

Test	Specification	
	Min	Max
CLASS 3 (solvent) / ACETONE	.	
MONOGRAPH EDITION		

***Spectrum Chemical Mfg Corp***

---

<i><b>Corporate Headquarters:</b></i>	<i><b>West Coast Facility:</b></i>
769 Jersey Ave.	14422 S. San Pedro St.
New Brunswick, NJ 08901	Gardena, CA 90248
732.214.1300	310.516.8000

## Certificate Of Analysis

Item Number	F1154	Lot Number	1JG0255
Item	Famotidine, USP	Manufacturer Lot	FMT/0919095
CAS Number	76824-35-6	Manufacturer Code	14107
Molecular Formula	C <sub>8</sub> H <sub>15</sub> N <sub>7</sub> O <sub>2</sub> S <sub>3</sub>	Molecular Weight	337.45

TEST	SPECIFICATION		RESULT
	MIN	MAX	
ASSAY (DRIED BASIS)	98.5	101.0 %	98.8 %
LOSS ON DRYING		0.5 %	0.05 %
RESIDUE ON IGNITION		0.1 %	0.03 %
ELEMENTAL IMPURITIES	AS REPORTED		NO ELEMENTAL IMPURITIES PRESENT
ORGANIC IMPURITIES:			.
Famotidine related compound D		0.3 %	<0.3 %
Famotidine related compound C		0.3 %	<0.3 %
Famotidine cyanoamidine		0.2 %	<0.15 %
Famotidine related compound F		0.1 %	<0.10 %
Famotidine amidine		0.2 %	<0.15 %
Famotidine related compound B		0.3 %	<0.15 %
Famotidine related compound E		0.3 %	<0.10 %
Any other individual impurity		0.1 %	<0.10 %
Total impurities		1.0 %	<0.8 %
IDENTIFICATION (FTIR)	SPECTRUM MATCHES REFERENCE		SPECTRUM MATCHES REFERENCE
APPEARANCE			WHITE POWDER
EXPIRATION DATE			31-AUG-2024
DATE OF MANUFACTURE			01-SEP-2019
RESIDUAL SOLVENTS	AS REPORTED		.
CLASS 2 (SOLVENT) / METHANOL	.		<3000 ppm
CLASS 3 (solvent) / ACETONE	.		<5000 ppm
MONOGRAPH EDITION			(USP) 42

Certificate of Analysis Results Entered By:

HBERMUDEZ  
Hernan Bermudez  
16-JUL-20 12:04:46

Certificate of Analysis Results Approved By:

HBERMUDEZ  
Hernan Bermudez  
16-JUL-20 12:05:26

Spectrum Chemical Mfg Corp  
14422 South San Pedro Street  
Gardena 90248 CA



**All pharmaceutical ingredients are tested using current edition of applicable pharmacopeia.**

**Read and understand label and SDS before handling any chemicals. All Spectrum's chemicals are for manufacturing, processing, repackaging or research purposes by experienced personnel only. It is the customer's responsibility to provide adequate hazardous material training and ensure that appropriate Personal Protective Equipment (PPE) is used before handling any chemical.**

The Elemental Impurities standards implemented by USP and other Pharmaceutical Compendia reflect a growing understanding of the toxicology of trace levels of elemental impurities that can remain in drug substances originating from either raw materials or manufacturing processes. Identifying and quantifying impurities can be critical to predicting the best possible patient outcomes. Elemental Impurities has been a requirement of all products meeting USP/NF, EP and BP monographs since January 1, 2018. More information can be found in USP sections <232> Elemental Impurities – Limits and <233> Elemental Impurities – Procedures. Data for drug substances furnished by Spectrum Chemical Mfg. Corp can be used to ensure that patient daily exposures by oral administration to the selected elements are not exceeded in the formulation of pharmaceutical products.

Spectrum Chemical Mfg. Corp. repackages Active Pharmaceutical Ingredient chemicals provided by other manufacturers and suppliers. For traceability purposes, Spectrum's Certificate of Analysis contains an identifier code unique to each manufacturer or supplier, as well as the chemical's lot number provided on the original manufacturer Certificate of Analysis. This material is manufactured by SMS Pharmaceuticals Limited at Unit-II, Plot No.24&24B and 36&37, S.V.Co-Operative Industrial Estate, Bachupally, Medchal-Malkajgiri District, Hyderabad, Telangana 500090, India. Copies of the original Certificate of Analysis are available upon request from your Spectrum Sales Representative or by calling Spectrum's Quality Department at 1-800-772-8786.

# SAFETY DATA SHEET

Preparation Date: 8/29/2017

Revision Date: 8/29/2017

Revision Number: G1

## 1. IDENTIFICATION

### Product identifier

**Product code:** F1154  
**Product Name:** FAMOTIDINE, USP

### Other means of identification

**Synonyms:** 3-(((2-((Aminoiminomethyl)amino)-4-thiazolyl)methyl)thio)-N-(aminosulfonyl)propanimidamide  
 3-(((2-((Diaminomethylene)amino)-4-thiazolyl)methyl)thio)-N-(sup 2)-sulfamoylpropionamide  
 N-Sulfamoyl-3-((2-guanidinothiazol-4-yl)methylthio)propionamide  
**CAS #:** 76824-35-6  
**RTECS #** UA2300000  
**CI#:** Not available

### Recommended use of the chemical and restrictions on use

**Recommended use:** Medication.  
**Uses advised against** No information available

**Supplier:** Spectrum Chemical Mfg. Corp  
 14422 South San Pedro St.  
 Gardena, CA 90248  
 (310) 516-8000.

**Order Online At:** <https://www.spectrumchemical.com>

**Emergency telephone number** Chemtrec 1-800-424-9300

**Contact Person:** Martin LaBenz (West Coast)

**Contact Person:** Ibad Tirmiz (East Coast)

## 2. HAZARDS IDENTIFICATION

### Classification

This chemical is not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Not a dangerous substance or mixture according to the Globally Harmonized System (GHS)

### Label elements

Not classified

### Hazards not otherwise classified (HNOC)

Not Applicable

### Other hazards

Not available

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Components	CAS-No.	Weight %
Famotidine	76824-35-6	100

### 4. FIRST AID MEASURES

#### First aid measures

<b>General Advice:</b>	National Capital Poison Center in the United States can provide assistance if you have a poison emergency and need to talk to a poison specialist. Call 1-800-222-1222.
<b>Skin Contact:</b>	Wash off immediately with soap and plenty of water removing all contaminated clothing and shoes. Get medical attention if irritation develops. Consult a physician if necessary.
<b>Eye Contact:</b>	Flush eyes with water for 15 minutes. Get medical attention if irritation occurs. If symptoms persist, call a physician.
<b>Inhalation:</b>	Move to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.
<b>Ingestion:</b>	Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person. Consult a physician if necessary.

#### Most important symptoms and effects, both acute and delayed

<b>Symptoms</b>	May cause eye/skin irritation. May cause abdominal pain, nausea, vomiting, diarrhea. May cause constipation. May cause muscle and joint pain. May cause loss of appetite. May cause muscle weakness. May cause drowsiness or dizziness. May cause headache. tiredness. Insomnia. Confusion. Dryness of mouth. May cause cardiovascular effects. Cardiac arrhythmias.
-----------------	--

#### Indication of any immediate medical attention and special treatment needed

<b>Notes to Physician:</b>	Treat symptomatically.
----------------------------	------------------------

#### Protection of first-aiders

First-Aid Providers: Avoid exposure to blood or body fluids. Wear gloves and other necessary protective clothing. Dispose of contaminated clothing and equipment as bio-hazardous waste.

### 5. FIRE-FIGHTING MEASURES

#### Extinguishing Media

<b>Suitable Extinguishing Media:</b>	Carbon dioxide (CO2). Dry chemical. Water spray mist or foam.
--------------------------------------	---

<b>Unsuitable Extinguishing Media:</b>	No information available.
--	---------------------------

#### Specific hazards arising from the chemical

<b>Hazardous Combustion Products:</b>	Carbon monoxide; Carbon dioxide; nitrogen oxides; sulfur oxides
<b>Hazardous Combustion Products:</b>	No information available.
<b>Specific hazards:</b>	May be combustible at high temperatures. Fine dust



dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.

### **Special Protective Actions for Firefighters**

**Specific Methods:**

No information available.

**Special Protective Equipment for Firefighters:**

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear

## **6. ACCIDENTAL RELEASE MEASURES**

### **Personal precautions, protective equipment and emergency procedures**

**Personal Precautions:**

Ensure adequate ventilation. Use personal protective equipment. Avoid contact with skin, eyes and clothing. Avoid dust formation. Remove all sources of ignition.

**Environmental precautions**

Prevent further leakage or spillage if safe to do so. Prevent product from entering drains.

### **Methods and material for containment and cleaning up**

**Methods for containment**

Stop leak if you can do it without risk. Cover with plastic sheet to prevent spreading.

**Methods for cleaning up**

Sweep up and shovel into suitable containers for disposal. Clean contaminated surface thoroughly.

## **7. HANDLING AND STORAGE**

### **Precautions for safe handling**

**Technical Measures/Precautions:**

Provide sufficient air exchange and/or exhaust in work rooms. Avoid dust formation. All equipment used when handling the product must be grounded. Keep away from incompatible materials.

**Safe Handling Advice**

Wear personal protective equipment. Avoid contact with skin, eyes and clothing. Keep away from heat and sources of ignition. Avoid dust formation. Do not ingest. Do not breathe dust. Handle in accordance with good industrial hygiene and safety practice.

### **Conditions for safe storage, including any incompatibilities**

**Technical Measures/Storage Conditions:**

Keep container tightly closed in a dry and well-ventilated place. Store at room temperature in the original container. Store away from incompatible materials. Protect from light. Sensitive to light. Store in light-resistant containers.

**Incompatible Materials:**

Strong oxidizing agents

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

### **Control parameters**

#### **National occupational exposure limits**

**United States**

Components	CAS-No.	OSHA	NIOSH	ACGIH	AIHA WEEL
Famotidine	76824-35-6	None	None	None	None

### Canada

Components	CAS-No.	Canada - Alberta	Canada - British Columbia	Canada - Ontario	Canada - Quebec
Famotidine	76824-35-6	None	None	None	None

### Australia and Mexico

Components	CAS-No.	Australia	Mexico
Famotidine	76824-35-6	None	None

### Appropriate engineering controls

#### Engineering measures to reduce exposure:

Ensure adequate ventilation. Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

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

#### Personal Protective Equipment

<b>Eye protection:</b>	Safety glasses with side-shields or Goggles
<b>Skin and body protection:</b>	Long sleeved clothing Chemical resistant apron Gloves
<b>Respiratory protection:</b>	Effective dust mask. Use a dust respirator under conditions where exposure to the substance is apparent (e.g. generation of high concentration of dust (dust clouds) , inadequate ventilation, development of respiratory tract irritation), and engineering controls are not feasible. Be sure to use an approved/certified respirator or equivalent.
<b>Hygiene measures:</b>	Avoid contact with skin, eyes and clothing. Wash hands before breaks and immediately after handling the product. When using, do not eat, drink or smoke.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Physical state:</b> Solid	<b>Appearance:</b> Crystalline powder.	<b>Color:</b> White. Pale Yellow.
<b>Odor:</b> Odorless.	<b>Taste</b> No information available.	<b>Formula:</b> C8H15N7O2S3
<b>Molecular/Formula weight:</b> 337.45	<b>Flammability:</b> No information available	<b>Flashpoint (°C/°F):</b> No information available.
<b>Flash Point Tested according to:</b> Not available	<b>Autoignition Temperature (°C/°F):</b> No information available	<b>Lower Explosion Limit (%):</b> No information available
<b>Upper Explosion Limit (%):</b> No information available	<b>Melting point/range(°C/°F):</b> 163-164 °C/325-327 °F	<b>Decomposition temperature(°C/°F):</b> No information available

**Boiling point/range(°C/°F):**

No information available

**Bulk density:**

No information available

**Density (g/cm3):**

No information available

**Specific gravity:**

No information available

**pH:**

No information available

**Vapor pressure @ 20°C (kPa):**

No information available

**Evaporation rate:**

No information available

**Vapor density:**

No information available

**VOC content (g/L):**

No information available

**Odor threshold (ppm):**

No information available

**Partition coefficient****(n-octanol/water):**

No information available

**Viscosity:**

No information available

**Miscibility:**

No information available

**Solubility:**

Very slightly soluble in water

Freely soluble in glacial acetic acid

Practically insoluble in Ethanol

Practically insoluble in Acetone

Practically insoluble in Ether

Practically insoluble in Ethyl Acetate

Practically insoluble in Chloroform

**10. STABILITY AND REACTIVITY****Reactivity**

No information available

**Chemical stability****Stability:**

Stable under recommended storage conditions.

**Possibility of Hazardous Reactions:** Hazardous polymerization does not occur**Conditions to avoid:**

Heat. Avoid dust formation. Exposure to light. Incompatible materials.

**Incompatible Materials:**

Strong oxidizing agents

**Hazardous decomposition products:**

Carbon monoxide. Carbon dioxide. Nitrogen oxides (NOx). Sulfur oxides.

**Other Information****Corrosivity:**

No information available

**Special Remarks on Corrosivity:** No information available**11. TOXICOLOGICAL INFORMATION****Information on likely routes of exposure****Principal Routes of Exposure:**

Ingestion. Inhalation.

**Acute Toxicity****Component Information**

Famotidine

CAS-No.	76824-35-6
---------	------------

**LD50/oral/rat** = 4049 mg/kg Oral LD50 Rat  
**LD50/oral/mouse** = 4686 mg/kg  
**LD50/dermal/rabbit** = No information available  
**LD50/dermal/rat** = No information available  
**LC50/inhalation/rat** = No information available  
**LC50/inhalation/mouse** = No information available  
**Other LD50 or LC50 information** = No information available

## Product Information

**LD50/oral/rat** =  
**VALUE- Acute Tox Oral** = 4049 mg/kg

**LD50/oral/mouse** =  
**Value - Acute Tox Oral** = 4686 mg/kg

**LD50/dermal/rabbit**  
**VALUE-Acute Tox Dermal** = No information available

**LD50/dermal/rat**  
**VALUE -Acute Tox Dermal** = No information available

**LC50/inhalation/rat**  
**VALUE-Vapor** = No information available  
**VALUE-Gas** = No information available  
**VALUE-Dust/Mist** = No information available

**LC50/Inhalation/mouse**  
**VALUE-Vapor** = No information available  
**VALUE - Gas** = No information available  
**VALUE - Dust/Mist** = No information available

## Symptoms

**Skin Contact:** May cause skin irritation.

**Eye Contact:** May cause eye irritation.

**Inhalation** May cause irritation of respiratory tract.

**Ingestion** May cause dry mouth. May cause nausea. May cause vomiting. May cause diarrhea. May cause constipation. May cause abdominal discomfort. May cause fatigue. May affect behavior/central nervous system (dizziness, headache). May affect the cardiovascular system (cardiac arrhythmias). May affect the cardiovascular system (palpitations). May affect the liver (increased hepatic enzymes). May affect liver. May affect behavior/central nervous system (somnolence). May cause muscle cramps. May cause joint pain. May affect behavior/central nervous system (confusion). May affect behavior/central nervous system (hallucinations, insomnia). May affect behavior/central nervous system (convulsions). May affect the liver and cause jaundice, a yellowing of the skin and/or eyes. May cause painful or difficult urination. May affect respiration (shortness of breath). May cause taste perversion. May cause skin rash, redness or itching.

**Aspiration hazard** No information available.

## Delayed and immediate effects as well as chronic effects from short and long-term exposure

**Chronic Toxicity** Prolonged or repeated ingestion may affect metabolism (cause anorexia, weight loss). Prolonged or repeated ingestion may affect the blood. Prolonged or repeated ingestion may cause paresthesia - a tingling, pricking, or numbness of the skin (known as the feeling of "pins and needles) generally of the hands and feet (extremities)).

**Sensitization:** No information available.

**Mutagenic Effects:** No information available

**Carcinogenic effects:** Not considered carcinogenic.

Components	CAS-No.	IARC	ACGIH - Carcinogens	NTP	OSHA HCS - Carcinogens	Australia - Notifiable Carcinogenic Substances	Australia - Prohibited Carcinogenic Substances
Famotidine	76824-35-6	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed

*ACGIH (American Conference of Governmental Industrial Hygienists)*

*IARC (International Agency for Research on Cancer)*

*NTP (National Toxicology Program)*

*OSHA (Occupational Safety and Health Administration of the US Department of Labor)*

**Reproductive toxicity** No data is available

**Reproductive Effects:** No information available

**Developmental Effects:** No information available

**Teratogenic Effects:** No information available

**Specific Target Organ Toxicity**

**STOT - single exposure** No information available.

**STOT - repeated exposure** No information available.

**Target Organs:** No information available.

## 12. ECOLOGICAL INFORMATION

**Ecotoxicity**

**Ecotoxicity effects:** No data available.

**Persistence and degradability:** No information available

**Bioaccumulative potential:** No information available.

**Mobility:** No information available.

## 13. DISPOSAL CONSIDERATIONS

**Disposal Methods**

**Waste from residues / unused products:**

Waste must be disposed of in accordance with Federal, State and Local regulation.

**Contaminated packaging:**

**Product code:** F1154

**Product name:** FAMOTIDINE, USP

7 / 11

Empty containers should be taken for local recycling, recovery or waste disposal

Components	CAS-No.	RCRA - F Series Wastes	RCRA - K Series Wastes	RCRA - P Series Wastes	RCRA - U Series Wastes
Famotidine	76824-35-6	None	None	None	None

#### 14. TRANSPORT INFORMATION

##### DOT

**UN-No:** Not Regulated  
**Proper Shipping Name:** No information available  
**Hazard Class:** No information available  
**Subsidiary Class** No information available  
**Packing group:** No information available  
**Emergency Response Guide Number** No information available  
**Marine Pollutant** No data available  
**DOT RQ (lbs):** No information available  
**Special Provisions** No Information available  
**Symbol(s):** No information available  
**Description:** No information available

##### TDG (Canada)

**UN-No:** Not Regulated  
**Proper Shipping Name:** No information available  
**Hazard Class:** No information available  
**Subsidiary Risk:** No information available  
**Packing Group:** No information available  
**Marine Pollutant** No Information available  
**Description:** No information available

##### ADR

**UN-No:** Not Regulated  
**Proper Shipping Name:** No information available  
**Hazard Class:** No information available  
**Packing Group:** No information available  
**Subsidiary Risk:** No information available

##### IMO / IMDG

**UN-No:** Not Regulated  
**Proper Shipping Name:** No information available  
**Hazard Class:** No information available  
**Subsidiary Risk:** No information available  
**Packing Group:** No information available  
**Marine Pollutant** No information available

##### RID

**UN-No:** Not Regulated  
**Proper Shipping Name:** No information available  
**Hazard Class:** No information available  
**Subsidiary Risk:** No information available  
**Packing Group:** No information available

##### ICAO

**UN-No:** Not Regulated  
**Proper Shipping Name:** No information available  
**Hazard Class:** No information available  
**Subsidiary Risk:** No information available  
**Packing Group:** No information available

**IATA**

**UN-No:** Not Regulated  
**Proper Shipping Name:** No information available  
**Hazard Class:** No information available  
**Subsidiary Risk:** No information available  
**Packing Group:** No information available  
**ERG Code:** No information available  
**Special Provisions** No information available

<b>15. REGULATORY INFORMATION</b>
-----------------------------------

**International Inventories**

Components	CAS-No.	U.S. TSCA	KOREA KECL	Philippines (PICCS)	Japan ENCS	CHINA	Australia (AICS)	EINECS-No.
Famotidine	76824-35-6	Not Listed	Present KE-01425	Not present	Not present	Not present	Present	Not present

**U.S. Regulations****California Prop. 65: Safe Drinking Water and Toxic Enforcement Act of 1986.****Chemicals Known to the State of California to Cause Cancer:**

This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

**Chemicals Known to the State of California to Cause Reproductive Toxicity:**

This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

Components	CAS-No.	Carcinogen	Developmental Toxicity	Male Reproductive Toxicity	Female Reproductive Toxicity:
Famotidine	76824-35-6	Not Listed	Not Listed	Not Listed	Not Listed

**CERCLA/SARA**

Components	CAS-No.	CERCLA - Hazardous Substances and their Reportable Quantities	Section 302 Extremely Hazardous Substances and TPQs	Section 302 Extremely Hazardous Substances and RQs	Section 313 - Chemical Category	Section 313 - Reporting de minimis
Famotidine	76824-35-6	None	None	None	None	None

**U.S. TSCA**

Components	CAS-No.	TSCA Section 5(a)2 - Chemicals With Significant New Use Rules (SNURS)	TSCA 8(d) -Health and Safety Reporting
Famotidine	76824-35-6	Not Applicable	Not Applicable

**Canada****WHIMIS 2015 - GHS Classifications**

WHMIS 2015 Hazard Classification Information:

Not a dangerous product according to HPR classification criteria.

**Canada Hazardous Products Regulation** This product has been classified according to the hazard criteria of the HPR (Hazardous Products Regulation) and the SDS contains all of the information required by the HPR

**WHMIS 1988 Hazard Class**

Non-controlled

**Canada Controlled Products Regulation:**

This product has been classified according to the hazard criteria of the CPR (Controlled Products Regulation) and the MSDS contains all of the information required by the CPR.

**Inventory**

Components	CAS-No.	Canada (DSL)	Canada (NDSL)
Famotidine	76824-35-6	Present	Not Listed

Components	CAS-No.	CEPA Schedule I - Toxic Substances
Famotidine	76824-35-6	Not listed
Components	CAS-No.	CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting
Famotidine	76824-35-6	Not listed

**EU Classification****EU GHS - SV - CLP 1272/2008**

Components	CAS-No.	EU GHS - SV - CLP (1272/2008)
Famotidine	76824-35-6	

**EU - CLP (1272/2008)****R-phrases(s)**

not determined (not applicable)

**S -phrase(s)**

none

Components	CAS-No.	Classification	Concentration Limits:	Safety Phrases
Famotidine	76824-35-6		No information	

The product is classified in accordance with Annex VI to Directive 67/548/EEC

**Indication of danger:**

Not dangerous

**16. OTHER INFORMATION**

**Preparation Date:** 8/29/2017  
**Revision Date:** 8/29/2017  
**Prepared by:** Sonia Owen

**Disclaimer:**

All chemicals may pose unknown hazards and should be used with caution. This Safety Data Sheet (SDS) applies only to the material as packaged. If this product is combined with other materials, deteriorates, or becomes contaminated, it may pose hazards not mentioned in this SDS. The physical properties reported in this SDS are obtained from the literature and do not constitute product specifications. Information contained herein does not constitute a warranty, whether expressed or implied, as to the safety, merchantability or fitness of the goods for a particular purpose. Spectrum Chemicals & Laboratory Products, Inc. assumes no responsibility for results obtained or for incidental or consequential damages,



including lost profits, arising from the use of these data. No warranty against infringement of any patent, copyright or trademark is made or implied. It shall be the user's responsibility to develop proper methods of handling and personal protection based on the actual conditions of use. While this SDS is based on technical data judged to be reliable, Spectrum assumes no responsibility for the completeness or accuracy of the information contained herein.

**End of Safety Data Sheet**



**Certification of Compliance with current Good Manufacturing Practices**

Dear Valued Customer:

Spectrum Chemical Mfg Corp certifies that the following product(s) is produced, processed, packaged and held in compliance with current Good Manufacturing Practices (cGMP) in accordance with the applicable parts of 21 CFR, parts 210 and 211 of the Code of Federal Regulations.

Catalog Number	Product Name
F1154	Famotidine, USP

Spectrum is an FDA registered and inspected Drug Establishment. Our United States Food and Drug Administration (USFDA) Registration numbers are as follows:

Spectrum-Gardena, CA: 2020632  
Spectrum-New Brunswick, NJ: 2246824

Thank you for your interest in Spectrum products. If we may be of further assistance, please feel free to contact the Quality Assurance department at 310-516-8000 or via email at [qualityassurance@spectrumchemical.com](mailto:qualityassurance@spectrumchemical.com)

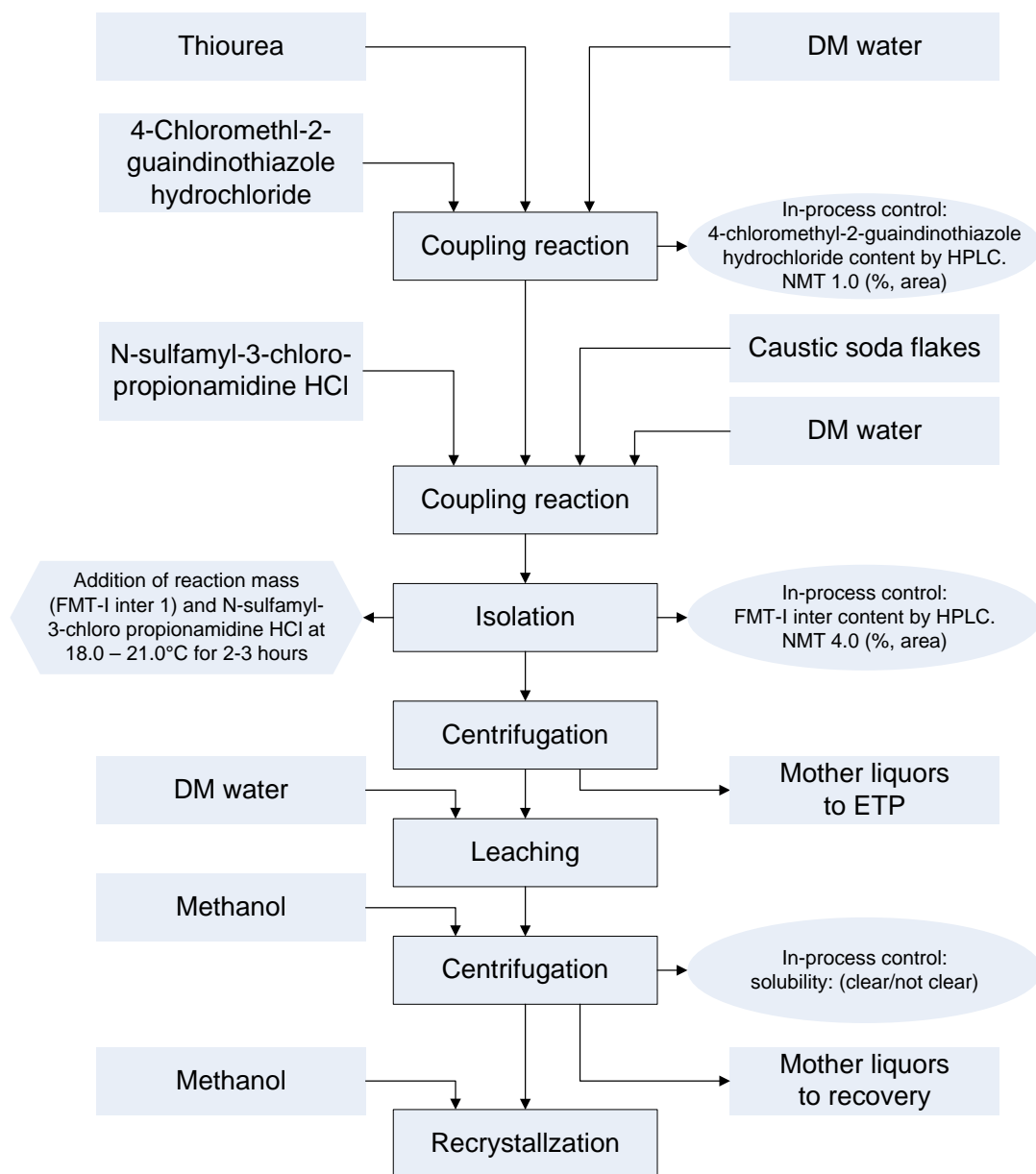
Sincerely,

A handwritten signature in black ink, appearing to read "Oralia Chavez", written in a cursive style.

Oralia Chavez  
Quality Assurance Specialist

## Manufacturing Process Flowchart

### Famotidine, USP - F1154



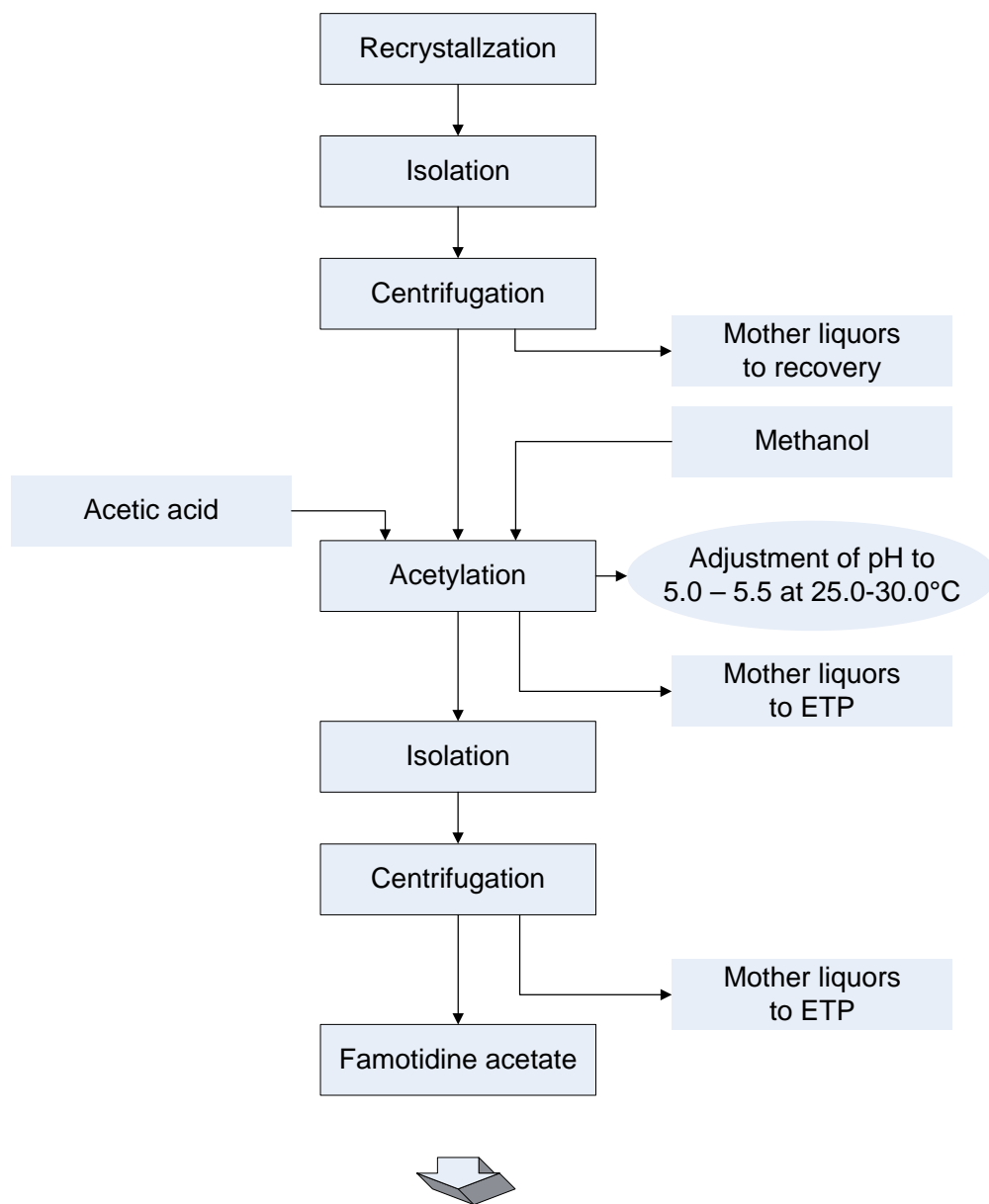
#### Spectrum Chemical Mfg Corp

##### Corporate Headquarters:

769 Jersey Ave.  
New Brunswick, NJ 08901  
732.214.1300

##### West Coast Facility:

14422 S. San Pedro St.  
Gardena, CA 90248  
310.516.8000



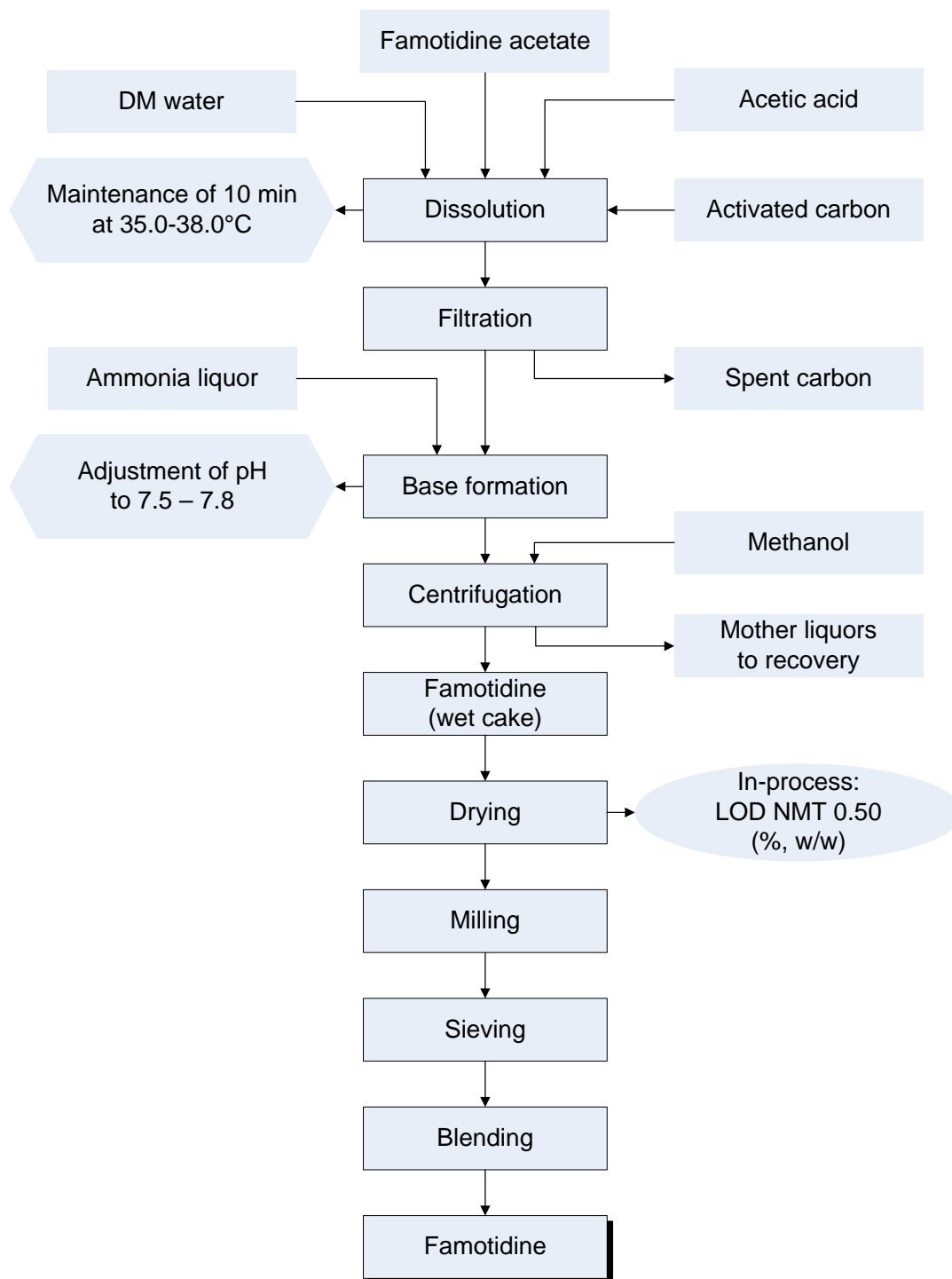
## ***Spectrum Chemical Mfg Corp***

### ***Corporate Headquarters:***

769 Jersey Ave.  
New Brunswick, NJ 08901  
732.214.1300

### ***West Coast Facility:***

14422 S. San Pedro St.  
Gardena, CA 90248  
310.516.8000



## ***Spectrum Chemical Mfg Corp***

### **Corporate Headquarters:**

769 Jersey Ave.  
New Brunswick, NJ 08901  
732.214.1300

### **West Coast Facility:**

14422 S. San Pedro St.  
Gardena, CA 90248  
310.516.8000

## **F1154, Famotidine, USP**

### **Source Statement**

The above mentioned catalog item is manufactured by chemical synthesis. No animal or plant derived products are used in the manufacturing process.

### **BSE/TSE Statement**

The above mentioned catalog item does not contain nor is manufactured using any animal derived products and is therefore, BSE/TSE free.

### **Allergen Statement**

The above mentioned catalog item does not contain any of the following:

- Milk
- Egg
- Fish
- Shellfish
- Tree Nuts
- Wheat
- Peanuts
- Soy
- Cereals containing Gluten
- Celery
- Mustard
- Sesame Seed
- Corn
- Latex
- Sulfites > 10 ppm

### **EU Fragrance Allergen Statement**

The above mentioned catalog item does not contain any of the 26 EU fragrance allergens listed in Annex III lines 67-92. These substances are not intentionally added to the following chemical and therefore are not expected to be present.

### **GMO Statement**

The above mentioned catalog item is manufactured without the use of genetically modified organisms and is therefore GMO free.

### **Melamine Statement**

The above mentioned catalog does not use or add melamine to the manufacturing process and is considered melamine-free.

## Nitrosamine Statement

Based on knowledge of the manufacturing process, nitrosamine impurities are not known or suspected to be present in this material.

## Animal Testing Statement

The above mentioned catalog item has not been tested on animals.

## Organic Compliance Statement

The above mentioned catalog item has not been produced using GMOs, irradiation, ethylene oxide (EtO) or sewage sludge.

## Shelf Life Statement

The above mentioned catalog item is typically assigned a shelf life of 60 months from the date of manufacture. The actual assigned shelf life for any specific lot should be referenced on the Certificate of Analysis.

## Other Chemicals Statement

Spectrum does not have any reason to suspect the above mentioned catalog item contains any of the following chemicals. This product does not come into contact with these chemicals during packaging or storage:

- |                     |                 |
|---------------------|-----------------|
| • Aflatoxins        | • Parabens      |
| • Antibiotics       | • Pesticides    |
| • Bisphenol A (BPA) | • Phthalates    |
| • CMR Substances    | • Preservatives |



**RE: Elemental Impurities - Famotidine, USP (Cat# F1154)**

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above material complies with the USP<232>, <233> Elemental Impurities and the ICH Q3D Elemental Impurities Guideline. The following elemental impurities are likely to be present:

Elemental Impurity		Class	Expected Concentration
Cadmium	Cd	1	< 0.5 ppm
Lead	Pb	1	< 0.5 ppm
Arsenic	As	1	< 1.5 ppm
Mercury	Hg	1	< 3.0 ppm
Cobalt	Co	2A	< 5.0 ppm
Vanadium	V	2A	< 10.0 ppm
Nickel	Ni	2A	< 20.0 ppm

Other elemental impurities considered by USP <232>, <233> and ICH Q3D which are not addressed in the above mentioned table are not likely to be present. These substances are not used in the production process, are not intentionally added or known to be present in the above mentioned material.

This information is subject to change and is intended for risk assessment only. It is responsibility of the end user to evaluate suitability of any chemical for the intended use as well as to assess compound-specific limits of daily intake of metal impurities. For lot-specific information, please refer to the respective Certificate of Analysis.

If you have any further questions, please contact us by telephone at 1(800)772-8786 Option 2, or by email at [TechServices@spectrumchemical.com](mailto:TechServices@spectrumchemical.com).

Sincerely,

Technical Services  
Spectrum Chemical Mfg. Corp.

**CORPORATE HEADQUARTERS**

769 Jersey Avenue

New Brunswick, NJ 08901

PHONE 732.214.1300

FAX 732.246.7132

**WEST COAST FACILITY**

14422 South San Pedro Street

Gardena, California 90248

PHONE 310.516.8000

FAX 310.516.9843





This document has been produced electronically and is valid without a signature.

CORPORATE HEADQUARTERS

769 Jersey Avenue

New Brunswick, NJ 08901

PHONE 732.214.1300

FAX 732.246.7132

WEST COAST FACILITY

14422 South San Pedro Street

Gardena, California 90248

PHONE 310.516.8000

FAX 310.516.9843



**RE: Residual Solvents - Famotidine, USP (Cat# F1154)**

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above mentioned catalog item complies with the requirements of USP <467> Residual Solvents and ICH Q3C Residual Solvents Guideline. The following solvents are likely to be present:

Residual Solvent	Class	Expected Concentration
Methanol	2	< 3000 ppm
Acetone	3	< 5000 ppm

No Class 1 or other solvents are used or produced in the manufacturing process of this material.

For lot-specific information, please refer to the respective Certificate of Analysis.

If you have any further questions, please contact us by telephone at 1(800)772-8786 Option 2, or by email at [TechServices@spectrumchemical.com](mailto:TechServices@spectrumchemical.com).

Sincerely,

Technical Services  
Spectrum Chemical Mfg. Corp.

This document has been produced electronically and is valid without a signature.

CORPORATE HEADQUARTERS

769 Jersey Avenue

New Brunswick, NJ 08901

PHONE 732.214.1300

FAX 732.246.7132

WEST COAST FACILITY

14422 South San Pedro Street

Gardena, California 90248

PHONE 310.516.8000

FAX 310.516.9843

## Label Information

The Spectrum label presents technical and safety information in an easily understood format. Our technical specialists stay abreast of the latest requirements of the Globally Harmonized System for Classification and Labelling of Chemicals (GHS), as well as the Occupational Safety and Health Administration (OSHA), the Food and Drug Administration (FDA) and other government regulatory agencies in order to ensure compliance, accuracy and concise hazard communication. Below you will find a typical label example for this catalog item.

**USE CARE:** This material has been evaluated per GHS/OSHA criteria and is not classified as hazardous. All chemicals may pose unknown hazards and must be used with caution. Use personal protection and safe handling methods consistent with proper workplace safety practices. Consult SDS for additional properties and precautions. If adverse reaction occurs seek medical attention.



**KEEP FROM CHILDREN**

**WARNING:**

Cancer and Reproductive Harm-  
www.P65Warnings.ca.gov

**F1154**

**SIZ SY**

### Famotidine

{3-[(2-Diaminomethyleneaminothiazol-4-yl)-methylthio]-N-sulfamoylpropionamide}

USP

CAS 76824-35-6

**CAUTION:** For manufacturing, processing, repacking, or for prescription compounding. Rx only.  
**Read and understand the label and Safety Data Sheet (SDS) prior to use.**

**Chemical Emergency: (800)424-9300**

www.SpectrumChemical.com

$C_8H_{15}N_7O_2S_3$  F.W. 337.45

Manufacturer/Supplier Code.....?  
Manufacturer Lot Number.....?

Assay (Dried Basis).....98.5-101.0%

**MAXIMUM LIMITS**

Loss on Drying.....	0.5%
Residue on Ignition.....	0.1%
Elemental Impurities.....	As reported
<b>Organic Impurities:</b>	
Famotidine Related Compound D.....	0.3%
Famotidine Related Compound C.....	0.3%
Famotidine Cyanoamide.....	0.2%
Famotidine Related Compound F.....	0.1%
Famotidine Amidine.....	0.2%
Famotidine Related Compound B.....	0.3%
Famotidine Related Compound E.....	0.3%
Any Other Individual Impurity.....	0.1%
Total Impurities.....	1.0%
Residual Solvents.....	To pass test

**LIGHT SENSITIVE:** Keep tightly closed in light-resistant containers.

Repackaged by Spectrum as:

G 11/J2GHS-A ? Lot No. XQ####

### Spectrum Chemical Mfg Corp

**Corporate Headquarters:**

769 Jersey Ave.  
New Brunswick, NJ 08901  
732.214.1300

**West Coast Facility:**

14422 S. San Pedro St.  
Gardena, CA 90248  
310.516.8000