

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)propionamide
 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

General Advice:	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.
Skin Contact:	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.
Eye Contact:	Flush eyes with water for 15 minutes. Get medical attention if irritation occurs. If symptoms persist, call a physician.
Inhalation:	Move to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.
Ingestion:	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

Symptoms	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.
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Indication of any immediate medical attention and special treatment needed

Notes to Physician:	Treat symptomatically.
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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

Suitable Extinguishing Media: Carbon dioxide (CO₂). Dry chemical. Water spray mist or foam.

Unsuitable Extinguishing Media: No information available.

Specific hazards arising from the chemical

Hazardous Combustion Products: Carbon monoxide; Carbon dioxide; nitrogen oxides; sulfur oxides

Hazardous Combustion Products: No information available.

Specific hazards: 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

- Eye protection:** Safety glasses with side-shields or Goggles
- Skin and body protection:** Long sleeved clothing
Chemical resistant apron
Gloves
- Respiratory protection:** 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.
- Hygiene measures:** 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

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

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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

15. REGULATORY INFORMATION

International Inventories

Components	CAS-No.	U.S. TSCA	KOREA KECL	Philippines (PICCS)	Japan ENCS	CHINA	Australia (AICS)	EINECS-No.
<i>Famotidine</i>	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:
<i>Famotidine</i>	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
<i>Famotidine</i>	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
<i>Famotidine</i>	76824-35-6	Not Applicable	Not Applicable

Canada**WHMIS 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-phrase(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,

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End of Safety Data Sheet