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Section 1 - Identification


- (a) **Product Identifier:** Famotidine Injection, USP
- (b) **Product Code:** 70860-751
70860-752
70860-753
- Common/Trade Name:** Famotidine Injection
- Chemical Name:** [1-Amino-3-[[[2-[(diaminomethylene)amino]-4-thiazolyl]-methyl]thio]propylidene] sulfamide
- Chemical Family:** Histamine receptor antagonist
- (c) **Product Use:** Pharmaceutical, Injectable
- Product Type:** Regulated Prescription Drug
- Container Information:** Vial
- (d) **Distributor:** Athenex Pharmaceutical Division, 10 N. Martingale Road, Suite 230, Schaumburg, IL 60173, 847-886-9515
- (e) **Emergency Telephone:** 855-273-0154

Section 2 - Hazards Identification

- (a) **GHS Classification of substance or mixture:** US OSHA: Not Classified

(b) Signal Word, Hazard statement(s), Symbol(s), and/or Precautionary statement(s):	
GHS Signal Word:	Not applicable
GHS Hazard Statement:	Not applicable
GHS Symbols:	Not applicable
GHS Precautionary Statements:	Not applicable
Other Hazards	Not applicable

- (d) **Unknown Acute Toxicity** N/A

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Section 3 – Composition / Information on Ingredients

Famotidine Injection, USP – 20 mg per 2mL (Preservative Free)


(a) Chemical Name	(b) Common Name / Synonym	% Composition or other measure	(c) CAS No.	(d) Impurities / Stabilizing Additives
[1-Amino-3-[[[2-[(diaminomethylene)amino]-4-thiazolyl]-methyl]thio]propylidene] sulfamide	Famotidine	10.0 mg/mL	76824-35-6	N/A
L-aspartic acid USP	L-aspartic acid	4.0 mg/mL	56-84-8	N/A
Mannitol USP	Mannitol	20.0 mg/mL	69-65-8	N/A
Water for Injection USP/BP/Ph. Eur	Water for Injection	q.s. to 1 mL	7732-18-5	N/A
Nitrogen Ph. Eur/USP-NF	Nitrogen	q.s.	7727-37-9	N/A

q.s. – Quantity Sufficient

Famotidine Injection, USP – 40 mg per 4mL and 200 mg per 20 mL (With Preservative)

(a) Chemical Name	(b) Common Name / Synonym	% Composition or other measure	(c) CAS No.	(d) Impurities / Stabilizing Additives
[1-Amino-3-[[[2-[(diaminomethylene)amino]-4-thiazolyl]-methyl]thio]propylidene] sulfamide	Famotidine	10.0 mg/mL	76824-35-6	N/A
L-aspartic acid USP	L-aspartic acid	4.0 mg/mL	56-84-8	N/A
Mannitol USP	Mannitol	20.0 mg/mL	69-65-8	N/A
Benzyl Alcohol USP-NF	Benzyl Alcohol	9.0 mg/mL	100-51-6	N/A
Water for Injection USP/BP/Ph. Eur	Water for Injection	q.s. to 1 mL	7732-18-5	N/A
Nitrogen Ph. Eur/USP-NF	Nitrogen	q.s.	7727-37-9	N/A

Section 4 – First Aid Measures

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- Eye Exposure:** Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
- Skin Exposure:** Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
- Ingestion:** Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.
- Injection:** In cases of accidental injection, wash and disinfect area, seek emergency medical attention.
- Inhalation:** Remove to fresh air and keep patient at rest. Seek medical attention immediately.
- Notes to Physician:** Treat symptomatically and supportively. See patient package insert in shipping carton for complete information.

Section 5 – Fire-fighting Measures

- (a) **Extinguishing Media** Use carbon dioxide, dry chemical, or water spray.
- (b) **Hazardous Combustion Products:** Formation of toxic gases is possible during heating or fire.
- (c) **Special Protective Equipment / Precautions:** During all fire-fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Section 6 - Accidental Release Measures

- Spill:** Personnel involved in clean-up should wear appropriate personal protective equipment. Minimize exposure.
- Contain the source of the spill or leak. Absorb spills with non-combustible absorbent material and transfer into a labeled container for disposal. Clean spill area thoroughly.
- Large spill: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

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Release to Air: Not available.

Release to Water: Not available. Refer to the local water authority; drain disposal is not recommended. Refer to local, state and federal guidelines.

Section 7 - Handling and Storage

General Handling: Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment. Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural wastewater and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Storage Conditions: Store Famotidine Injection, USP refrigerated between 2° and 8°C (36° and 46°F).

Section 8 - Exposure Controls / Personal Protection

(a) Exposure Limits

Compound	Issuer	Type	Exposure Limit
Famotidine	OSHA	PEL	NE
	ACGIH	TLV	NE
	AIHA	WEEL	NE

Notes:


OSHA PEL: US Occupational Safety and Health Administration – Permissible Exposure Limit
 ACGIH TLV: American Conference of Governmental Industrial Hygienists – Threshold Limit Value.
 AIHA WEEL: Workplace Environmental Exposure Level

(b) Engineering Controls

No special ventilation requirements. Good general ventilation should be sufficient to control worker exposure to airborne contaminants. If this product contains ingredients with exposure limits, use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure below any recommended or statutory limits.

Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation.


(c) Individual Protection Measures

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Respiratory Protection:	Use a properly fitted, air-purifying or supplied air respirator complying with an approved standard if a risk assessment indicates this is necessary. Respirator selection must be based on known or anticipated exposure levels, the hazards of the product and the safe working limits of the selected respirator.
Eye Protection:	Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: safety glasses with side shields.
Skin Protection:	Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product. Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
Other Protective Equipment:	Protective Latex or Nitrile gloves
Additional Exposure Precautions:	Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Ensure that eyewash stations and safety showers are close to the workstation location.

Section 9 - Physical and Chemical Properties

(a) Appearance	clear, colorless solution
(b) Odor	No odor
(c) Odor Threshold	Not available
(d) pH	5.0-5.6
(e) Melting Point:	Not available
(f) Initial Boiling Point:	Not available
(g) Flash Point	Not available
(h) Evaporation Rate:	Not available
(i) Flammability	Not available
(j) Upper Lower Flammability or Explosion Limits	Not available

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(k)	Vapor Pressure:	Not available
(l)	Vapor Density:	Not available
(m)	Relative Density	Not available
(n)	Solubility(ies)	Freely soluble in water
(o)	Partition Coefficient: n-octanol/water	Not available
(p)	Auto-ignition Temperature	Not available
(q)	Decomposition Temperature	Not available
(r)	Viscosity	Not available

Section 10 - Stability and Reactivity

(a)	Reactivity	No specific test data related to reactivity available for this product or its ingredients.
(b)	Chemical Stability	The product is stable.
(c)	Possibility of Hazardous Reactions	Under normal conditions of storage and use, hazardous reactions will not occur.
(d)	Conditions to Avoid	Not determined
(e)	Incompatible Materials	Reactive or incompatible with the following materials: oxidizing materials.
(f)	Hazardous Decomposition Products	Under normal conditions of storage and use, hazardous decomposition products should not be produced.


Section 11 - Toxicological Information

(a)	Likely Routes of Exposure	Dermal contact. Eye contact. Inhalation. Ingestion.
(b)	Symptoms related to the physical, chemical and toxicological characteristics	No known significant effects or critical hazards.
(c)	Delayed and immediate effects and chronic effects from short and long term exposure	No known significant effects or critical hazards.

(d) Acute Toxicity

Not determined for the product formulation or active ingredient dexmedetomidine. By analogy, information for the racemic medetomidine hydrochloride mixture is as follows:

Component	Type	Route	Species	Dosage
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Famotidine	LD ₅₀	Oral	Rat	4049 mg/kg
	LD ₅₀	Para-periosteal	Rat	254 mg/kg
	LD ₅₀	Intraperitoneal	Rat	800 mg/kg
	LD ₅₀	Oral	Mouse	4686 mg/kg
	LD ₅₀	Intravenous	Mouse	254 mg/kg
Mannitol	LD ₅₀	Oral	Rat	13500 mg/kg
	LD ₅₀	Oral	Mouse	22 g/kg

(e) Hazardous Chemical Listings

NTP: Not Listed **IARC:** Not Listed **OSHA:** Not Listed

Section 12 - Ecological Information

(a) Ecotoxicity	No data available.
(b) Persistence and degradability	No data available.
(c) Bioaccumulative potential	No data available.
(d) Mobility in soil	No data available.
(e) Other Adverse Effects	No data available.


Section 13 - Disposal Considerations

Waste Disposal: Dispose of any cleanup materials and waste residue according to all applicable laws and regulations.

Section 14 - Transport Information

DOT: Not regulated as a dangerous good.
IATA: Not regulated as a dangerous good.
IMDG: Not regulated as a dangerous good.

(a) UN Number	N/A
(b) UN Proper Shipping Name	N/A
(c) Transport Hazard Class(es)	N/A
(d) Packing Group	N/A
(e) Environmental Hazards	N/A
(f) Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code)	N/A
(g) Special Precautions	N/A

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Section 15 - Regulatory Information

Below is selected regulatory information chosen primarily for possible Athenex Pharmaceutical Division usage. 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. Regulations:

- TSCA – Not regulated
- CERCLA - Not on this list
- SARA 302 - Not on this list
- SARA 311/312: Not on this list
- SARA 313 - Not on this list
- OSHA – Not on this list

Section 16 - Other Information


As of the date of effectiveness, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information contact:

Athenex Pharmaceutical Division
 10 N. Martingale Road, Suite 230
 Schaumburg, IL 60173
 847-886-9515

Glossary: This glossary contains definitions of general terms used in SDSs. Not all of these Glossary Terms will apply to this SDS.

ACGIH	American Conference of Governmental Industrial Hygienists
AICS	Australian Inventory of Chemical Substances
AIHA	American Industrial Hygiene Association
ANSI	American National Standards Institute
CAS Number	Chemical Abstract Service Registry Number
CERCLA	Comprehensive Environmental Response Compensation and Liability Act (of
CHAN	Chemical Hazard Alert Notice
CHEMTREC	Chemical Transportation Emergency Center
DOT	Department of Transportation
DSL	Domestic Substances List
ECHA	European Chemicals Agency

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EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
EPA	Environmental Protection Agency
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
HEPA	High Efficiency Particulate Air (Filter)
HMIS	Hazardous Materials Identification System
IARC	International Agency for Research on Cancer
ICAO/IATA	International Civil Aviation Organization/International Air Transport
IMO	International Maritime Organization
KOW	Octanol/Water Partition Coefficient
LEL	Lower Explosive Limit
MSDS	Material Safety Data Sheet
MSHA	Mine Safety and Health Administration
NA	Not Applicable, except in Section 14 where NA = North America
NE	Not Established
NADA	New Animal Drug Application
NAIF	No Applicable Information Found
NCI	National Cancer Institute
NDSL	Non-Domestic Substances List
NFPA	National Fire Protection Association
NIOSH	National Institute for Occupational Safety and Health
NPDES	National Pollutant Discharge Elimination System
NOS	Not Otherwise Specified
NTP	National Toxicology Program
OSHA	Occupational Safety and Health Administration
OEL	Occupational Exposure Limit
PEL	Permissible Exposure Limit (OSHA)
RCRA	Resource Conservation and Recovery Act
RQ	Reportable Quantity
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
SDS	Safety Data Sheet
STEL	Short Term Exposure Limit
TLV	Threshold Limit Value (ACGIH)
TPQ	Threshold Planning Quantity
TSCA	Toxic Substances Control Act
TWA	Time Weighted Average/8 Hours Unless Otherwise Noted
UEL	Upper Explosive Limit
UN	United Nations
USP	United States Pharmacopeia
WEEL	Workplace Environmental Exposure Level (AIHA)
WHMIS	Workplace Hazardous Materials Information System

Signature Manifest

Document Number: SDS039
Title: Famotidine Injection, USP

Revision: 01

All dates and times are in Eastern Standard Time.

SDS Creation

Change Request

Name/Signature	Title	Date	Meaning/Reason
Michael Scribner (MSCRIBNER)	Director of Corporate Quality		
Michael Spengler (MSPENGLER)	QC Applications Specialist		
Christopher Martensen (CMARTENSEN)	Quality Engineer-CSV		
Emily Means (EMEANS)	Quality Engineer	28 Apr 2020, 12:19:15 PM	Approved

Dept Approval

Name/Signature	Title	Date	Meaning/Reason
John Andre (JANDRE)	Regulatory Affairs Consultant	05 May 2020, 08:51:43 AM	Approved

Final QA Approval/Set Effective Date

Name/Signature	Title	Date	Meaning/Reason
Sheila Moran (SMORAN)	VP of Quality Assurance	06 May 2020, 12:18:47 PM	Approved