



WEST-WARD

Material Safety Data Sheet

Revision date: 1/19/2012

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1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Product name: Famotidine Injection

Product Codes: NDC 0641-6021-01, NDC 0641-6021-10, NDC 0641-6022-01
NDC 0641-6022-25, NDC 0641-6023-01, NDC 0641-6023-25

Chemical Family: Histamine receptor antagonist

Product Type: Regulated Prescription Drug

Container Information: Famotidine Injection (non-preserved), 2 ml single Dose Vial.
Famotidine Injection (preserved), 4 ml and 20 ml Multidose Vials.

Product Use: Pharmaceutical.

Supplier:
WEST-WARD PHARMACEUTICALS
EATONTOWN, NJ 07724

Emergency telephone number: CHEMTREC: USA & Canada (800) 424-9300 OUTSIDE USA +1 703-527-3887

2. COMPOSITION/INFORMATION ON INGREDIENTS

Component	Weight %	UN Number:	Classification:
Famotidine 76824-35-6	1	None	None
Aspartic Acid 56-84-8	<1	None	None
Mannitol 69-65-8	2	None	None
Benzyl Alcohol 100-51-6	0-0.9	UN1986 (flammable, toxic); UN1987 (alcohol); UN3065 (alcoholic beverages)	Xn;R20/22 S:2-26
Water 7732-18-5	>96	None	None

3. HAZARDS IDENTIFICATION

Emergency overview: Product contains no specific hazards other than therapeutic effects.

Principle routes of exposure: Absorbed through skin. Eye contact. Ingestion.

Inhalation: Inhalation not likely under normal use conditions.

Ingestion: Practically non-toxic if swallowed. Gastrointestinal effects (may include nausea/vomiting, abdominal pain, diarrhea, dry mouth, colic). Nervous system effects (headache, dizziness, light headedness).

Skin contact: May cause skin irritation.

Eye contact: May cause eye irritation.

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4. FIRST AID MEASURES

Inhalation:	If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Seek medical attention.
Skin contact:	In case of contact, immediately flush skin with plenty of water. Remove contaminated clothing and shoes. Wash clothing before reuse. Thoroughly clean shoes before reuse. Get medical attention
Ingestion:	Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. If large quantities of this material are swallowed, call a physician immediately.
Eye contact:	In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention
Notes to physician:	See patient package insert in shipping carton for complete information.

5. FIRE FIGHTING MEASURES

Suitable extinguishing media:	Use foam or all purpose dry chemicals to extinguish.
Special protective equipment for firefighters:	Fire fighters should wear positive pressure self-contained breathing apparatus (SCBA) and full turnout gear.
Specific methods:	No information available.
Flash point:	Not determined
Autoignition temperature:	Not available
Flammable limits in air-lower (%):	Not available
Flammable limits in air-upper (%):	Not available

6. ACCIDENTAL RELEASE MEASURES

Personal precautions:	Keep unnecessary personnel away. Use suitable protective equipment (Section 8). Follow all fire fighting procedures (Section 5).
Environmental precautions:	No information available.
Methods for cleaning up:	If emergency personnel are unavailable, contain spilled material. For small spills add absorbent (soil may be used in the absence of other suitable materials) scoop up material and place in a sealed, liquid-proof container for disposal. For large spills dike spilled material or otherwise contain material to ensure runoff does not reach a waterway. Place spilled material in an appropriate container for disposal.

7. HANDLING AND STORAGE

Handling:

Technical measures/precautions: Wash thoroughly after handling.

Storage:

Technical measures/Storage conditions: Keep containers tightly closed in a cool, well-ventilated place. Store between 2-8 °C (35.6 to 46.4 °F).

Incompatible products: No special restrictions on storage with other products.

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8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Occupational Exposure Limits

Component	OSHA- Time Weighted Average:	OSHA- Short Term Exposure Limit:	OSHA- Ceiling Limits	ACGIH- Time Weighted Average:	ACGIH- Short Term Exposure Limit:	ACGIH- Ceiling Limit Value:
Famotidine 76824-35-6	None	None	None	None	None	None
Aspartic Acid 56-84-8	None	None	None	None	None	None
Mannitol 69-65-8	None	None	None	None	None	None
Benzyl Alcohol 100-51-6	None	None	None	None	None	None
Water 7732-18-5	None	None	None	None	None	None

Engineering measures: No special containment is required. Provide general or local exhaust ventilation.

Personal protective equipment:

Respiratory protection: No personal respiratory protective equipment normally required.

Hand protection: Use chemical resistant, impervious gloves.

Skin and body protection: Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits).

Eye protection: Eye protection not required for normal final product use. Safety glasses with side-shields are recommended for laboratory and manufacturing use.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state:	Liquid
Appearance:	Aqueous solution.
Color:	Clear
Odor:	Not available.
pH:	4.5 - 5.9
Molecular weight:	Not applicable
Boiling point/range:	Not available.
Melting point/range:	Not available.
Density:	Not available.
Vapor pressure:	Not available.
Evaporation rate:	Not available.
Solubility:	Soluble in water.
Partition coefficient (n-octanol/water):	Not available.
Viscosity:	Not available.
% Volatile by Volume:	Not available.

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10. STABILITY AND REACTIVITY

Stability:	Stable under recommended storage conditions.
Polymerization:	Not applicable
Hazardous decomposition products:	Not available.
Materials to avoid:	Not available.

11. TOXICOLOGICAL INFORMATION

Component	LD50s and LC50s
Famotidine 76824-35-6	Oral LD50 Rat = 4049 mg/kg Oral LD50 Mouse = 4686 mg/kg Intravenous LD50 Rat = 204 mg/kg Intravenous LD50 Mouse = 254 mg/kg
Aspartic Acid 56-84-8	None
Mannitol 69-65-8	Oral LD50 Rat = 13500 mg/kg Oral LD50 Mouse = 22 gm/kg
Benzyl Alcohol 100-51-6	Oral LD50 Rat = 1230 mg/kg Oral LD50 Mouse = 1360 mg/kg Dermal LD50 Rabbit = 2 gm/kg
Water 7732-18-5	Oral LD50 Rat: >50000 mg/kg

Acute toxicity:	Gastrointestinal effects (may include nausea/vomiting, abdominal pain, diarrhea, dry mouth, colic). Nervous system effects (headache, dizziness, light headedness).
Chronic toxicity:	Contains material which may cause damage to the following organs: skin, eye, lens or cornea.
Carcinogenic effects:	Not classified or listed by IARC, NTP, OSHA, EU and ACGIH. Not carcinogenic at all dose levels evaluated based on animal data.
Mutagenic effects:	Not mutagenic in a standard battery of genetic toxicological tests.
Reproductive toxicity:	No impairment to fertility based on animal data. Not considered fetotoxic based on animal data. See patient package insert for additional information.
FDA Pregnancy Catagory	B

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12. ECOLOGICAL INFORMATION

Environmental properties:

Component	Ecotoxicity - Water Flea Data	Fish Species Ecotoxicity	Ecotoxicity - Freshwater Algae Data	Ecotoxicity - Microtox Data
Famotidine 76824-35-6	None.	None.	None.	None.
Aspartic Acid 56-84-8	None.	None.	None.	None.
Mannitol 69-65-8	None.	None.	None.	None.
Benzyl Alcohol 100-51-6	23 mg/L EC50 48 h	10mg/LLC50Lepomis macrochirus96h 460mg/LLC50Pimep hales promelas96h	35 mg/L 3 h	50mg/LEC50Photobacte rium phosphoreum5min 63.7mg/LEC50Photobact erium phosphoreum15min 63.7mg/LEC50Photobact erium phosphoreum5min 71.4mg/LEC50Photobact erium phosphoreum30min
Water 7732-18-5	None.	None.	None.	None.

Ecotoxicity effects: No data available

Bioaccumulation: No data available

13. DISPOSAL CONSIDERATIONS

Waste Classification: Not regulated.

Waste from residues / unused products: Waste disposal must be in accordance with appropriate Federal, State, and local regulations.

14. TRANSPORT INFORMATION

DOT:

DOT shipping name:	None
UN Number:	None
DOT Packing Group:	None
DOT Hazard class:	None

TDG (Canada):

TDG Proper shipping name:	None
TDG UN/NA Number:	None
TDG Packing Group:	None
TDG Hazard class:	None

ADR/RID:

ADR Official Transport Name:	None
ADR Proper shipping name:	None

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14. TRANSPORT INFORMATION

ADR UN/NA number: None
ADR Hazard Class: None

ICAO / IATA:

IATA Proper shipping name: None
IATA UN NUMBER: None
IATA Primary Hazard: None
IATA Packing group: None
ICAO ERG Code: None

IMO / IMDG:

IMDG Proper Shipping Name: None
IMDG Hazard Class and Division: None
IMDG Packing Group: None
IMDG Subsidiary Risks: None

15. REGULATORY INFORMATION

U.S. Regulations:

TSCA Inventory List - The product is exempt from TSCA, it is FDA Regulated

OTHER REGULATIONS:

Japanese Inventory (ENCS) This product does not comply with JPENCS

Component	Weight %	RCRA Status:	CERCLA Reportable Quantity:	CERCLA/SARA - 302 Ext. haz. substances:	Listed as Sara 313 title III:
Famotidine	1	Not Listed	Not Listed	Not Listed	Not Listed
Aspartic Acid	<1	Not Listed	Not Listed	Not Listed	Not Listed
Mannitol	2	Not Listed	Not Listed	Not Listed	Not Listed
Benzyl Alcohol	0-0.9	Not Listed	Not Listed	Not Listed	Not Listed
Water	>96	Not Listed	Not Listed	Not Listed	Not Listed

STATE REGULATIONS:

Component	California Prop 65:	Minnesota Right-To-Know:	Florida Right-to-Know Reporting List:	Rhode Island Right-to-Know List:	Massachusetts Right-to-Know List:	Pennsylvania Right-to-Know:	New Jersey Right-to-Know:
Famotidine	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Aspartic Acid	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Mannitol	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Benzyl Alcohol	Not Listed	Present	Not Listed	Not Listed	Present	Present	sn 2079
Water	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed

CANADIAN REGULATIONS:

Canada DSL Inventory List - This product complies with DSL

EU EINECS List - This product does not comply with EINECS

Risk Phrases:

Not determined

Safety Phrases:

Not Determined

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16. OTHER INFORMATION

This data sheet contains changes from the previous version in section(s):

Updated company name from Baxter to West-Ward. Updated NDC codes

Additional information:

Not Available.

Prepared by:

West-Ward Pharmaceuticals

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End of safety data sheet

Product name: Famotidine Injection