

FAMOTIDINE INJECTION

Date Prepared: 06/01/2001

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1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Product Identifier: **Pepcid**

General Use: Histamine H2 antagonist

MANUFACTURER

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(708) 450-7500

2. COMPOSITION/INFORMATION ON INGREDIENTS

Component: **Benzyl Alcohol**

CAS Registry #: 100-51-6

OSHA PEL: NE	mg/m3	OSHA PEL: NE	ppm
ACGIH TLV: NE	mg/m3	ACGIH TLV: NE	ppm
STEL: NE	mg/m3	STEL: NE	ppm

Percent of Product: 0.9%

Note: 9 mg/ml, 730902 preservative free

Component: **Famotidine**

CAS Registry #: 76824-35-6

OSHA PEL: NE	mg/m3	OSHA PEL: NE	ppm
ACGIH TLV: NE	mg/m3	ACGIH TLV: NE	ppm
STEL: NE	mg/m3	STEL: NE	ppm

Percent of Product: NG

Note: 10 mg/ml

Component: **L- aspartic acid**

CAS Registry #: 56-84-8

OSHA PEL: NE	mg/m3	OSHA PEL: NE	ppm
ACGIH TLV: NE	mg/m3	ACGIH TLV: NE	ppm
STEL: NE	mg/m3	STEL: NE	ppm

Percent of Product: NG

Note: 4 mg/ml

Component: **Mannitol**

CAS Registry #: 69-65-8

OSHA PEL: NE	mg/m3	OSHA PEL: NE	ppm
ACGIH TLV: NE	mg/m3	ACGIH TLV: NE	ppm
STEL: NE	mg/m3	STEL: NE	ppm

Percent of Product: NG

Note: 20 mg/ml

Component: **Water for Injection**

CAS Registry #: 7732-18-5

OSHA PEL: NE	mg/m3	OSHA PEL: NE	ppm
ACGIH TLV: NE	mg/m3	ACGIH TLV: NE	ppm
STEL: NE	mg/m3	STEL: NE	ppm

Percent of Product: NG

Note: QS to volume

3. HAZARD IDENTIFICATION

PRIMARY ROUTES OF EXPOSURE - Inhalation, Eye/Skin Absorption and Ingestion.

CHEMICAL LISTING AS CARCINOGEN:

<u>COMPONENT</u>	<u>CAS No.</u>	<u>NTP</u>	<u>IARC</u>	<u>OSHA</u>
Benzyl Alcohol	100-51-6	NO	NO	NO
Famotidine	76824-35-6	NO	NO	NO
L- aspartic acid	56-84-8	NO	NO	NO
Mannitol	69-65-8	NO	NO	NO
Water for Injection	7732-18-5	NO	NO	NO

4. EMERGENCY AND FIRST AID PROCEDURES

Inhalation: Move person to fresh air immediately. Give artificial respiration and cardiopulmonary resuscitation (CPR) if required. Seek medical attention.

Ingestion: Flush mouth out with water immediately. Seek medical attention.

Skin Contact: Remove contaminated clothing immediately. Flush area with water for at least 15 minutes. Seek medical attention.

Eye Contact: Immediately flush with water for at least 15 minutes. Seek medical attention.

For Adverse Drug Reaction Information call (800) 551-7176.

5. FIRE FIGHTING MEASURES

Fire and Explosion Data:

Closed Cup Flash Pt.	NE
Open Cup Flash Pt.	NE
Fire Point	NE
Autoignition	NE
Lower Explosion Limit	NE
Upper Explosion Limit	NE

GENERAL HAZARD: When heated to decomposition it emits toxic fumes.

FIRE FIGHTING INSTRUCTION: Water spray, dry chemical, carbon dioxide or foam as appropriate.

FIRE FIGHTING EQUIPMENT: Wear self-contained breathing apparatus and protective clothing.

HAZARDOUS COMBUSTION PRODUCTS: Smoke, and toxic fumes of Cl₂.

6. ACCIDENTAL RELEASE MEASURES

CLEAN-UP: Wear recommended personal protective equipment. Use absorbent towels or booms to clean-up spill. Wipe surfaces clean and wash with soap and water.

7. HANDLING AND STORAGE

When handling pharmaceutical products, avoid all contact and inhalation of dust, fumes, mist, and/or vapors associated with the product. Store at 2° - 8°C (36° - 46°F) ; If solution freezes, bring to room temperature; allow sufficient time to solubilize all the components.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

ENGINEERING CONTROLS:

General room ventilation is usually satisfactory, use local exhaust ventilation when necessary.

PERSONAL PROTECTION:

Respirators - With satisfactory ventilation, respiratory protection not usually required.

Eyes - Safety glasses or goggles recommended.

Gloves - Disposable latex gloves recommended.

Clothing - Disposable garments if direct skin contact is anticipated.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance/Odor other characteristics: Clear, Colorless Solution

Boiling Point: NE

Vapor Density: NE

Melting Point: NE

Percent Volatiles: NE

Freezing Point: NE

pH: 5.0 - 5.7

Vapor Pressure: NE

Molecular Weight: 337.45

Note:

Solubility: Very slightly soluble in water

10. STABILITY AND REACTIVITY

Stability - Stable.

Conditions/Materials to Avoid - None. Store at 2° - 8°C (36° - 46°F) ; If solution freezes, bring to room temperature; allow sufficient time to solubilize all the components.

Hazardous Polymerization - Will not occur.

11. TOXICOLOGY INFORMATION

SIGNS & SYMPTOMS OF OVEREXPOSURE MAY INCLUDE:

This product is intended for therapeutic use only when prescribed by a physician. Potential adverse reactions from prescribed doses and overdoses are described in the package insert. Occupational exposure has not been fully investigated.

MEDICAL CONDITIONS GENERALLY RECOGNIZED AS BEING AGGRAVATED BY EXPOSURE: Pre-existing skin and respiratory conditions.

IMMEDIATE EFFECTS: Eye, skin and respiratory irritation may occur.

DELAYED EFFECTS: None Known.

12. TRANSPORT INFORMATION

UN/NA Number: NA

DOT Hazard Class: NA

Shipping Name: NA

Shipping Label: NA

13. WASTE DISPOSAL

Waste Disposal - Dispose of in accordance with federal, state and local regulations.

14. OTHER INFORMATION

KEY TO ABBREVIATIONS:

ACGIH - American Conference of Governmental Industrial Hygienists

HEPA - High-Efficiency Particulate Air

IARC - International Agency for Research on Cancer

NA - Not Applicable

NE - Not Established

NG - Not Given

NIOSH - National Institute for Occupational Safety and Health

NTP - National Toxicology Program

OSHA - Occupational Safety and Health Administration

PEL - Permissible Exposure Limit

PPM - Parts Per Million

QS - Quantity Sufficient

RCRA - Resource Conservation and Recovery Act

STEL - Short Term Exposure Limit

TLV - Threshold Limit Value

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